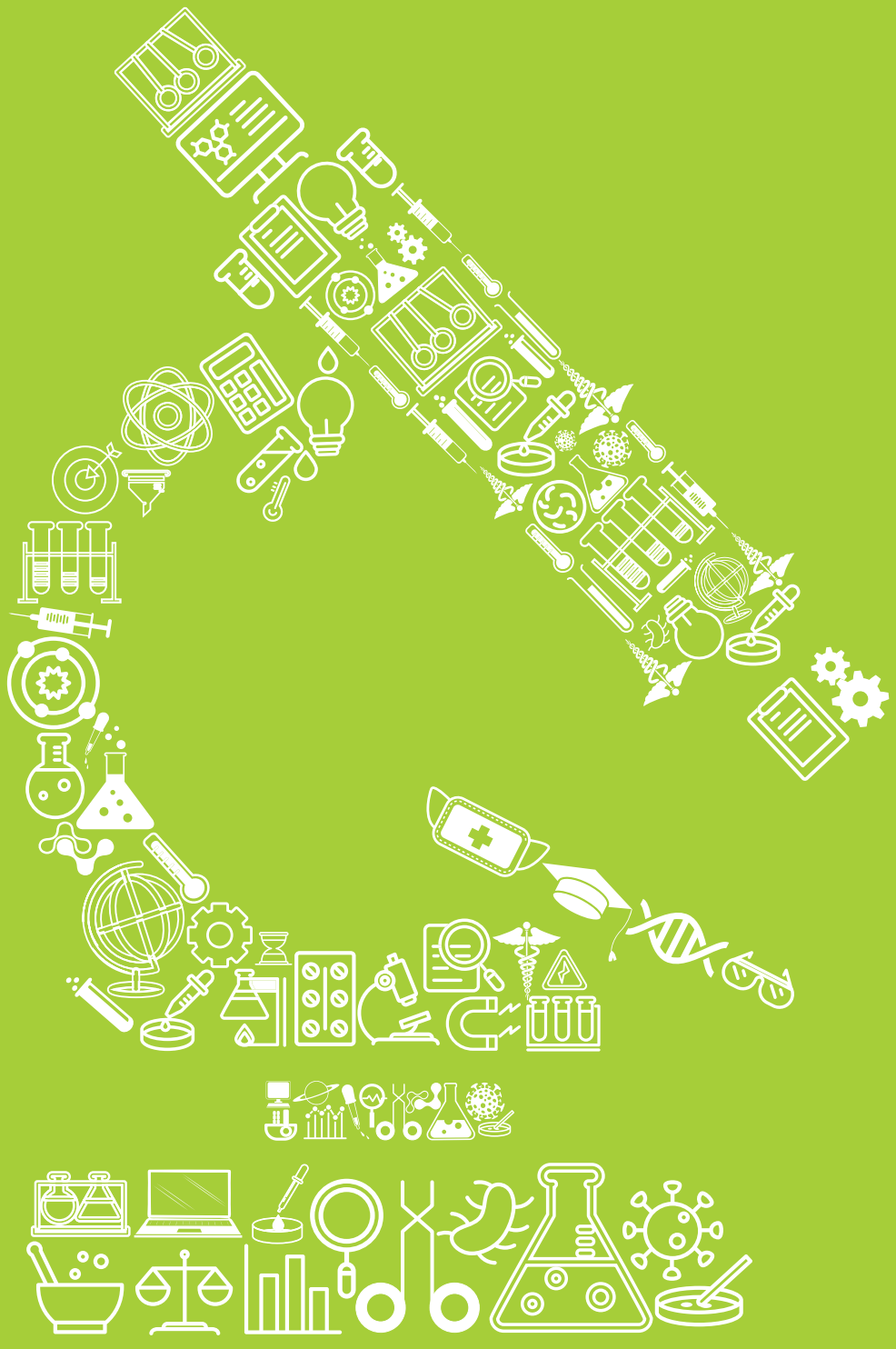
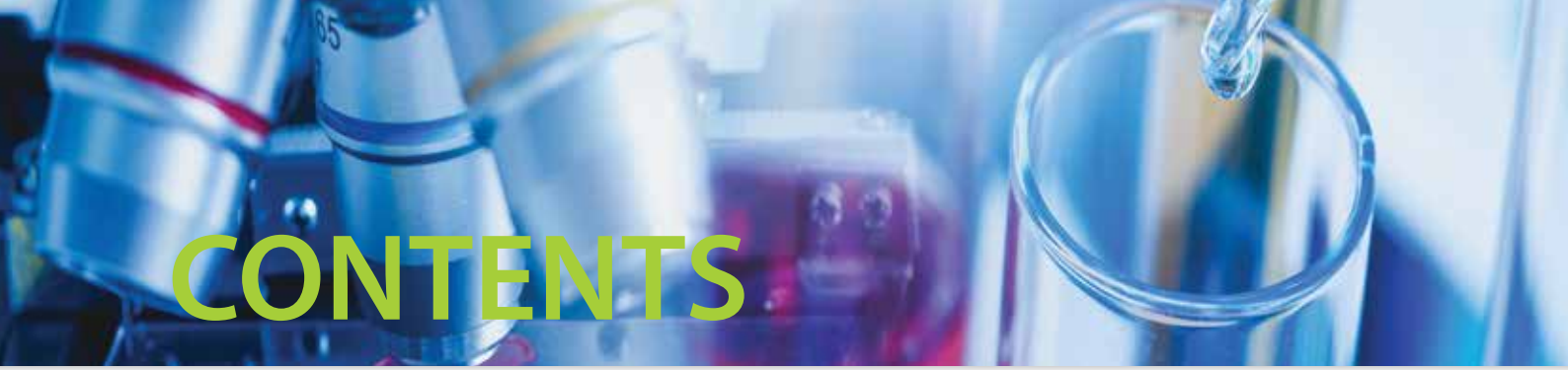
NATIONAL HEALTH
LABORATORY SERVICE

ANNUAL REPORT
2020/2021





CONTENTS

Financial highlights (2020/2021)

The National Health Laboratory Service (NHLS) generated a surplus of R54.3 million for the financial year.

The NHLS maintained an unqualified audit report for the 2020/21 financial period.

The NHLS' assets increased from a restated R7.0 billion to R7.3 billion.

Turnover grew from R9.3 billion to R10.7 billion.

Revenue for COVID-19 testing amounted to R1.9 billion, with over 4 million tests conducted between 1 April 2020 and 31 March 2021.

Performance highlights (non-financial 2020/2021)

The NHLS acted swiftly in preparation for **COVID-19.** The organisation started with two laboratories testing for COVID-19. By the end of the financial year, it had 128 laboratories dedicated to COVID-19 testing nationwide.

A total of **67 mobile laboratory** units were deployed across the country to fight the spread of COVID-19.

A total of **52 laboratories** have maintained or improved their accreditation from the previous year.

There were 91 South African National Accreditation System (SANAS)- accredited laboratories.

The NHLS published **673 articles** in peer-reviewed journals against a target of 620.

The occupational health and safety information system (OHASIS), which supports surveillance and compliance with occupational and environmental health and safety (OEHS), was extensively adapted to cater for new challenges posed by COVID-19. Further enhancements were made to cater for the unique needs posed by the NHLS' laboratory environment.

The Division of Biosafety and Biosecurity was instrumental in initiatives that included training for laboratory staff , and preparation of **SARS-CoV-2 virus** isolation and proliferation.

Nineteen laboratories received initial accreditation in the year under review.

PART A
GENERAL INFORMATION

1.1 GENERAL INFORMATION

Registered name:	National Health Laboratory Service (NHLS)
Legal status:	Schedule 3A public entity
Practice Number:	PR5200296
Registered office address:	1 Modderfontein Road Rietfontein Sandringham Johannesburg 2000
Postal address:	Private Bag X8, Johannesburg, 2131
Contact telephone number:	011 386 6000
Email address:	enquiries@nhls.ac.za
Website address:	http://www.nhls.ac.za
Company Secretary:	Adv Mpho Mphelo
External auditors:	Nexia SAB&T
Bankers:	First National Bank Limited, Rand Merchant Bank Limited, Investec Limited and Nedbank Limited

1.2 ABBREVIATIONS AND ACRONYMS

AAR	Academic Affairs and Research
AARMS	Academic Affairs and Research Management System
AARQA	Academic Affairs, Research and Quality Assurance
AIDS	Acquired Immune Deficiency Syndrome
AGSA	Auditor-General of South Africa
AMR	Antimicrobial Resistance
APP	Annual Performance Plan
ARC	Audit and Risk Committee
ART	Antiretroviral therapy
ASLM	African Society for Laboratory Medicine
AST	Aspartate Transaminase
ARAOH	African Regional Association of Occupational Health
AUDA	African Union Development Agency
AVE	Advertising Value Equivalent
CCMI	Competition Commission Market Inquiry
CD4	Cluster of differentiation 4
CDC	Centres for Disease Control and Prevention
CDW	Central Data Warehouse
CED	Centre for Enteric Diseases
CE-IVD	European Conformity – in vitro diagnostic
CEO	Chief Executive Officer
CEZPD	Centre for Emerging Zoonotic and Parasitic Diseases
CHARM	Centre for Healthcare-Associated Infections and Antimicrobial Resistance
CHBAH	Chris Hani Baragwanath Academic Hospital
CHAI	Clinton Health Access Initiative
CHE	Council on Higher Education
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CMSA	Colleges of Medicine of South Africa
COO	Chief Operations Officer
CPD	Continuing professional development
CQI	Continuous quality improvement
CrAg	Cryptococcal antigen
CRDM	Centre for Respiratory Diseases and Meningitis
CRP	C-reactive protein
CTIA	Cape Town International Airport
DAFF	Department of Agriculture Forestry and Fishery
DCS	Department of Correctional Services
DCS	Distributed computer system
DEL	Department of Employment and Labour
DoH	Department of Health
DMP	Diagnostic Media Products
DNA	Deoxyribonucleic acid
DPHSR	Division of Public Health Surveillance and Response
DSI	Department of Science and Innovation
DST	Drug susceptibility testing
DTG	Dolutegravir
ECHO	Project Extension for Community Healthcare Outcomes
ECM	Enterprise content Management
EDTA	Ethylenediaminetetraacetic acid
EID	Early infant diagnosis
ERP	Enterprise resource planning
EQA	External quality assessment
EXCO	Executive Management Committee
FBC	Full Blood Count
FDA	Food and Drug Administration
FETP	Field Epidemiology Training Programme
FinCom	Financial Committee
FIND	Foundation for Innovative New Diagnostics
FIOH	Finnish Institute of Occupational Health
FPD	Foundation for Professional Development
GAM	Global AIDS Monitoring
GFO	Grants Finance Office

GIS	Geographic information system
GLASS	Global Antimicrobial Resistance Surveillance System
GRAP	Standards of Generally Recognised Accounting Practice
HIV	Human immunodeficiency virus
HIV-PCR	human immunodeficiency virus - Polymerase chain reaction
HPCSA	Health Professions Council of South Africa
HPRS	Health Patient Registration System
HTA	Health Technology Assessment
IALCH	INkosi Albert Luthuli Central Hospital
IARC	International Agency for Research on Cancer
ICT	Information and communications technology
IEC	International Electrotechnical Commission
IKM	Information and Knowledge Management
IMT	Incident Management Team
IQC	Independent quality control
ISO	International Organization for Standardization
IT	Information technology
ITGC	Information Technology Governance Committee
IVD	In-vitro device
King IV	King Code of Governance Principles
KPI	Key performance indicators
LAM	Lipoarabinomannan
LIS	Laboratory Information System
MAC	Ministerial Advisory Committee
MDR	Multidrug-resistant
MEC	Member of the Executive Council
MALDI-TOF	Matrix Assisted Laser Desorption/Ionization
MMed	Master of Medicine
MMPA	Mine Medical Professionals Association
MoU	Memorandum of understanding
MTBC	Mycobacterium tuberculosis complex
MTB/RIFC	Mycobacterium tuberculosis/rifampicin
NAPC	National Academic and Pathology Committee
NAPHISA	National Public Health Institute of South Africa
NCCC	National COVID-19 Command Council
NCD	Non -communicable diseases
NCOH	National Centre for Occupational Health
NCR	National Cancer Registry
NDoH	National Department of Health
NDP	National Development Plan
Nedlac	National Economic Development and Labour Council
NEHAWU	National Education, Health and Allied Workers' Union
NEPAD	New Partnership for Africa's Development
NHA	National Health Act
NHI	National Health Insurance
NHLS	National Health Laboratory Service
NHRC	National Health Research Committee
NICD	National Institute for Communicable Diseases
NIH	National Institutes of Health
NIOH	National Institute for Occupational Health
NIOSH	National Institute for Occupational Safety and Health
NMC	Notifiable Medical Conditions
NPG	National Pathology Group
NPP	National Priority Programmes
NRF	National Research Foundation
OECD	Organisation for Economic Cooperation and Development
OEHS	Occupational and Environmental Health and Safety
OHASIS	Occupational Health and Safety Information System
OHS	Occupational Health and Safety
O.P.D.	Out Patient Department
PCR	Polymerase chain reaction

pct	procalcitonin
PEPFAR	United States President's Emergency Plan for AIDS Relief
PFMA	Public Finance Management Act
PHC	Primary healthcare centre
PIVOTAL	Professional, vocational, technical and academic learning
PPE	Personal Protective Equipment
PLWHIV	People living with HIV
PMC	Peri-mining communities
PMS	Post-market Surveillance
POCT	Point-of-care testing
POE	Point of Entry testing
PPO Serve	Professional Provider Organisation Services
PSC	Plasma Separation Card
PTS	Proficiency testing schemes
PwC	PricewaterhouseCoopers Inc
QA	Quality Assurance
QCMD	Quality Control for Molecular Diagnostics
QMS	Quality management system
R&D	Research and Development
REDCap	Research Data Capture
RFQ	Request for Quote
RFH	Rheumatoid Factor
RHRC	Remuneration and Human Resources Committee
RIC	Research and Innovation Committee
RSV	Respiratory syncytial virus
RT-PCR	Real-time polymerase chain reaction
RVFV	Rift Valley Fever Virus
SACCESS	South African Collaborative COVID-19 Environmental Surveillance
SACMC	South African COVID-19 Modelling Consortium
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authorities
SAMA	South African Medical Association
SMS	short message service
SAMRC	South African Medical Research Council
SANAS	South African National Accreditation System
SAPPHGenE	South Africa-Pittsburgh Public Health Genomic Epidemiology Research Training Programme
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SASOHN	South African Society of Occupational Health Nursing Practitioners
SASOM	South African Society of Occupational Medicine
SAVP	South African Vaccine Producers
SDG	Sustainable Development Goals
SDW	Statistical Data Warehouse
SKC	Scientific knowledge centre
SLMTA	Strengthening Laboratory Management Towards Accreditation
SMS	Short message service
SOE	State-owned enterprise
SOP	Standard operating procedure
STI	Sexually transmitted infection
TB	Tuberculosis
TDM	Therapeutic Drug Monitoring
ToR	Terms of reference
TWG	Technical Working Group
UI	User Interface
USAID	United States Agency for International Development
UNAIDS	Joint United Nations Programme on HIV/AIDS
VDPV1	Vaccine-derived Polio Virus Type 1
VDPV2	Vaccine-derived Polio Virus Type 2
VL	Viral Load
VPN	Virtual Private Network
WDGMC	Wits Donald Gordon Medical Centre
WHO	World Health Organization
WSP	Workplace Skills Plan
WGS	Whole-genome Sequencing
XDR	Extensive drug resistance

1.3 FOREWORD BY THE CHAIRPERSON

Prof Eric Buch
Chairperson

Introduction

The financial year under review has been a challenging one for the National Health Laboratory Service. Despite this, we created significant value for our stakeholders, namely the National Department of Health, and the provincial departments of Health. We have embraced agility and adaptability to ensure that we remain at the forefront of delivering quality testing for COVID-19 in the fight against the spread of the pandemic in South Africa.

This annual report is feedback to our stakeholders on the work done by the NHLS in the 2020/21 financial year in pursuing its mandate. It is an appraisal of the extent to which the organisation has managed to go about implementing the strategy, as well as the 2019/20 Annual Performance Plan (APP). The report provides a comprehensive overview of the activities of the NHLS, as well as financial and non-financial performance for the 2020/21 financial year. Work done in the period under review took place against the backdrop of increased expectations amid a constrained environment due to the COVID-19 pandemic.

The NHLS provides laboratory and related public health services to over 80% of the population through a national network of laboratories. Our specialised institutes include the National Institute for Communicable Diseases (NICD), the National Institute for Occupational Health (NIOH) and the South African Vaccine Producers (SAVP), as our subsidiary. The NHLS has laboratories in all nine provinces in the country, employing approximately 8 000 people. Its activities comprise diagnostic laboratory services, research, teaching and training, and production of sera for anti-snake and other venom, reagents and media.

The primary responsibility of the Board is to provide an informed and objective oversight of the application of the NHLS' mandate through delivering on the annual plan and the performance of the organisation. Under the leadership of the Chief Executive Officer, Dr Kamy Chetty, several impactful decisions have been made to steer the organisation towards a value-adding trajectory for the future of healthcare in South Africa.

The NHLS is mandated to:

- provide cost-effective and efficient health laboratory services to all public-sector healthcare providers;
- support and conduct health research; and
- provide training for health science education in conjunction with medical faculties at universities and universities of technology.

The NHLS also plays a major role in:

- COVID-19 testing in South Africa;
- public health in South Africa through epidemiology, surveillance and outbreak response activities;
- the national antiretroviral rollout programme through Cluster of Differentiation 4 (CD4) and viral load studies and HIV treatment monitoring;

- diagnostic testing for non-communicable disease
- tuberculosis (TB) diagnosis and treatment monitoring;
- the screening for cervical cancer; and
- the support of occupational health services.

Strategic overview

Strategically, the organisation is tasked with meeting its APP goals and targets, aligned with government's overall service delivery goals and deliverables. As the government moves to implement the National Health Insurance (NHI), the NHLS is required to improve all levels of service delivery to provide efficient and cost-effective laboratory testing. The NHLS executes its mandate and supports this national agenda in a focused and structured manner through the following five programmes:

Laboratory Service

The NHLS performed the majority of South Africa's COVID-19 tests through its 128 dedicated COVID-19 laboratories countrywide. While COVID-19 tests were more urgent by nature, the NHLS continued with its traditional tests for Human Immunodeficiency Virus (HIV), TB and cervical cancer for the public health system, through its network of laboratories countrywide. Operational efficiency and timely services are not only critical to the management of these diseases, but will also be prevalent when the NHI is fully operational.

Academic Affairs, Research and Quality Assurance

The Academic Affairs, Research and Quality Assurance Department continuously fosters excellent relationships with health science faculties at medical universities, comprehensive universities and universities of technology across the country. During the year under review, ongoing quality assurance efforts were supplemented by SANAS assessments to improve the quality of service and turnaround times of tests performed at our laboratories.

Surveillance of Communicable Diseases

The COVID-19 pandemic has repositioned the strategic importance of the NICD in detecting, containing and responding to infectious disease threats in South Africa, the Southern African Development Community (SADC) region and Africa. As a credible health partner to the national Department of Health (DoH), the World Health Organization (WHO) and the Africa Centers for Disease Control and Prevention (CDC), the institution provides technical support and continual surveillance of communicable diseases, outbreak response, specialised diagnostic services, research and training, capacity building and provincial epidemiology services. It furthermore provides the global health community with valuable information on communicable diseases. National Treasury funds core surveillance activities through the provision of a conditional grant, while select research projects are grant-funded from external agencies and donor funds. The NICD comprises seven disease-focused centres, including a transversal Division of Public Health Surveillance and Response (DPHSR). The 500-strong staff complement includes pathologists, scientists, epidemiologists, medical technologists and technicians, and surveillance officers.

Occupational Health and Safety

The National Institute for for Occupational Health plays an important role in supporting government's efforts in occupational health. It is recognised as a centre of excellence for occupational health and functions as a national and regional source of knowledge and expertise to the South African government, industry and labour, the SADC countries and the African region. It provides advice and assistance, conducts research and develops capacity, through teaching and training, to promote healthy conditions in workplaces and improve the health of workers.

Administration

All aspects of the organisation's service delivery are underpinned by effective administration provided through a range of support services, such as organisational development, human resources and labour relations, information technology, property management, security, legal services, communication and integrated planning. Four key programmes are in place to keep these vital elements of the organisation on track: Financial Management, Governance and Compliance, Information and Technology, and Human Resources Management.

Strategic relationships

The NHLS has strong relationships with industry, the national and provincial departments of Health, as well as with continental bodies like the African Union Development Agency New Partnership for Africa's Development (AUDA-NEPAD), the South African Society of Occupational Medicine (SASOM), the African Regional Association of Occupational Health (ARAOH), the South African Society of Occupational Health Nursing Practitioners (SASOHN), the Southern African Institute for Occupational Hygiene (SAIOH) and the Mine Medical Professionals Association (MMPA). During the year under review, collaborations with government departments such as the departments of Employment and Labour, and Mineral Resources and Energy were pivotal in mitigating the spread of COVID-19.

The NHLS Board

The NHLS is committed to principles and practices that provide our stakeholders with the assurance that the organisation is managed soundly and ethically. We have established a management model that governs and provides guidance for the way that all employees interact with our various stakeholder groups. As such, we put in place a robust and appropriate set of checks and balances. It was as a result of these robust and appropriate measures that the NHLS conducted an internal audit on the procurement of services and equipment (including personal protective equipment (PPE)) for the COVID-19 emergency during the first half of 2020. Subsequently, PricewaterhouseCoopers Inc (PwC) was appointed to conduct a forensic investigation into emergency procurement. PwC was further requested to conduct a forensic investigation into the transactions between the NHLS and the six particular companies that had been identified by the law enforcement agencies.

The year ahead

The NHLS will continue to invest in the modernisation of the Information Technology (IT) system to ensure that it has a state-of-the-art infrastructure. It is committed to fostering an environment that supports research, with particular emphasis on innovative approaches to diagnostics, surveillance and the strengthening of health systems to support national programmes.

Conclusion and acknowledgements

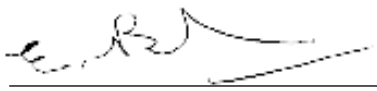
What is also noteworthy is that, over this period, the NHLS maintained an unqualified audit opinion from the Auditors, which speaks to the quality of leadership of the institution. As the NHLS, we are proud of these achievements and will endeavour to build on them to leave a lasting legacy for future generations, both at an institutional and a societal level.

Furthermore, the NHLS was able to achieve 80% of its set targets in the 2020/21 financial year, despite the pressures presented by the COVID-19 outbreak.

I would like to express my sincere gratitude and that of the entire Board to the Minister of Health and Deputy Minister for their unwavering support of the NHLS. I am also thankful to the Director-General of Health for being a pillar of support and wisdom. We would like to indicate our appreciation to the Members of the Executive Council (MECs) for Health and heads of provincial departments of Health, who recognised the fact that the NHLS is a national asset, and as such, prioritised payments to the NHLS, despite prevailing financial challenges.

With that said, I wish to extend a word of gratitude to my fellow Board members who, through their expertise and commitment, ease the task of providing leadership and oversight to the NHLS. The Board is determined to support the management and staff of the NHLS to achieve more of the objectives outlined in the founding legislation of the NHLS. This would ensure maximum impact as we move further from outcomes to focusing on the impact of our programmes, especially in the context of the shrinking fiscal envelope. At the heart of any organisation is its staff.

My sincere gratitude goes to all NHLS' employees, who put the organisation and its role in service of our country first, and who continually strive for excellence and efficiency. Our duty as the Board is to provide value for what is effectively public money that has been entrusted to the NHLS and the Board to ensure good governance and oversight, with a strategy to accomplish this.



Prof Eric Buch
Chairperson of the NHLS Board

1.4 CHIEF EXECUTIVE OFFICER'S OVERVIEW

Dr Kamy Chetty
Chief Executive Officer

Introduction

It gives me great pleasure to present the 2020/21 annual report. The past year once again presented the health sector with challenges and opportunities, which the NHLS embraced with vigour. The financial year under review was largely characterised by the impacts of the COVID-19 pandemic. My appreciation goes to our Board and the executive management for their guidance and support, to our staff members for their tireless and unwavering commitment to service delivery, and to the National Department of Health and the provincial departments of health for their collaborative efforts to deliver on our COVID-19 testing mandate.

Despite the challenges presented by the pandemic, the overall organisational performance was excellent in 2020/21 with 80% of the annual predetermined objectives (targets) being achieved. Once again, we received an unqualified audit from the Auditors. We are proud of this achievement, which is the third consecutive positive outcome for the organisation and a reflection of our commitment to upholding ethical operations. This was achieved through the selfless leadership, commitment and support of our Board, executive management and staff, to whom we are very thankful.

The year under review was challenging, as we had to deal with the reality of the pandemic. Our response to COVID-19 was two-pronged. Internally, we upscaled the number of tests we conduct. This was made possible by increasing our extraction and polymerase chain reaction (PCR) equipment, exploring alternative extraction methods, advocating for a better supply of test kits, and utilising more targeted, focused testing that allows for the better use of the limited resources available to fight the COVID-19 pandemic. Externally, we supported the national DoH and the provincial departments of health with mobile testing units. The NHLS and its divisions - the NICD and the NIOH – have played a pivotal role in surveillance, monitoring, provision, data analysis and modelling. The expertise provided has been recognised both nationally and globally. These are but a few of the responses we have implemented.

Financial overview

The NHLS ended the 2020/21 financial year with a cash bank balance of R3 billion. However, this was less than it was at the end of the previous financial year. The reduction in the cash bank balance was due to increased costs that were incurred in relation to the COVID-19 pandemic.

The NHLS generated a surplus for the year, amounting to R54.3 million compared to a restated R1.1 billion surplus in the previous financial year. The NHLS experienced a 5% decrease in total volumes compared to the prior financial period. This is due to the COVID-19 pandemic, which negatively affected the consumption of pathology services by the NHLS' customers.

The NHLS' revenue grew by 15% compared to the prior year. This is due to test revenue generated from COVID-19 testing. The increase in revenue was largely due to COVID-19 tests. Despite the NHLS' reduced cash balance, it has successfully demonstrated its ability to pay its current liabilities out of current assets. The current ratio exceeds the standard ratio of 2:1.

The NHLS' creditor days have increased to 35 days, which is a marginal increase from the prior year. The two main drivers for the increase are increased procurement due to the COVID-19 pandemic, as well as the severe business disruption that COVID-19 has caused to both the NHLS and its suppliers. The NHLS collected R9.2 billion from provincial departments compared to R8.7 billion in the prior year.

As of 31 March 2021, trade debtors amount to R5.1 billion. The majority of this debt pertains two Provincial Departments of Health. The majority of the debt is owed by KwaZulu-Natal and Gauteng. The settlement agreement that was reached with the Gauteng Department of Health has seen a reduction in the debt owed by Gauteng. The negotiations with the KwaZulu-Natal Department of Health regarding the settlement of overdue amounts owed to the NHLS are ongoing. The NHLS will continue to engage the provinces concerning the timely payments of debt in arrears.

The NHLS' current liabilities have increased from R1.7 billion to R1.9 billion (a 12% increase) due to an increase in the provision of leave pay. Creditors' days have also been increased from 28 days to 35 days.

I am pleased with the progress that has been made concerning our finances. This is a reflection of the commitment of the NHLS' employees to the financial sustainability of the organisation, the effectiveness of measures that were put in place and the disciplined application of the cost management strategies that were implemented to strengthen our finances to enable us to remain financially sustainable in our operations.

People management

The NHLS staff turnover rate, excluding the conclusion and termination of contracts, was 4.4%, which is considered a very healthy turnover for any organisation.

The NHLS continued to fulfil its role in promoting and prioritising skills development through the analysis of its employees' skills needs by implementing the Workplace Skills Plan. Multiple learning programmes are offered through short learning programmes, in-service conferences and congresses, as well as continuing professional development programmes to enable the organisation to comply with legislation, improve the quality of its services, ensure business continuity and assist in the mitigation of risks.

Improvements in systems

The IT Department continues its aim of becoming a strategic enabler to the business operations of the NHLS. To achieve this, several projects were initiated to ensure that the organisation eventually transforms into a digital business. This includes the deployment of Microsoft 365. The implementation of this project, was aimed at improving collaboration between the NHLS' employees and stakeholders, such as the national DoH, through the deployment of tools such as Microsoft Teams, OneDrive, SharePoint Online and Exchange Online to improve the availability of the critical email service. In the 2019/20 financial year, the project of refreshing the Oracle enterprise resource planning (ERP) system infrastructure was implemented as a first phase, which included the reimaging of the infrastructure and the upgrading of the database to improve the application's performance. The second phase of the project was successfully implemented in 2020/21, in which the Oracle e-business suite was upgraded to the latest version in alignment with global standard business processes to improve the NHLS' business processes. The network infrastructure and data storage capacity remains at the top of the list of IT priorities to address the NHLS' business challenges. To this end, Phase 2 of the LAN Refresh Project was initiated, which aims to address the ailing infrastructure risk.

The Information and Knowledge Management Unit continued to provide enterprise content management (ECM) solutions as part of the digital business transformation journey by rolling out and maintaining digitalisation solutions. As such, the ECM's asynchronous scanning solution, integrated with TrakCare, contributed to making laboratory request forms available and accessible electronically in the NHLS' laboratories across the country, resulting in improved auditing processes, the resolution of billing disputes and the continuous payment of invoices to the NHLS.

In the Laboratory Information System (LIS) environment, a patient communication system was developed to allow for the sending of Short Message Service (SMS) messages to patients. Patients who have been tested for COVID-19 rely on feedback from healthcare workers to know their results. To reduce the pressure on healthcare workers, patients are informed of their results by SMS. As new instruments and tests were implemented in the laboratories, the LIS developed, tested and implemented interfaces to allow for the rapid uploading of results onto the TrakCare laboratory system. To assist with surge testing, interfaces to several public and private partner laboratories were implemented in rapid succession. This allowed for the digital exchange of laboratory orders and results, and improved turnaround times.

The Corporate Data Warehousing Unit managed to develop six dashboards. These were developed in response to the business requirement to monitor the NHLS' response to COVID-19. A pre ISO 9001:2015 internal quality audit was performed. System availability

for Informatica (extract, transform and load) and Netezza (data warehouse) was above 98%. It managed to deliver on all data requests: microstrategy reports and dashboard distributions, scheduled data extracts and interface deliveries, legal data requests, research data requests, DoH operational reports and internal NHLS operational reports.

Going forward, the NHLS will be focusing on strengthening its information technology systems, among others. This will be achieved by investing in IT infrastructure.

Service delivery

In the year under review, the NHLS performed more tests compared to the previous financial year. It is mandated by the national DoH to provide services aimed at improving TB and HIV acquired immunodeficiency syndrome (AIDS) management for vulnerable communities in South Africa. During 2020/21, 5.8 million HIV viral load tests were performed, compared to 5.7 million during 2019/20, constituting a 1.85% increase. Of these, 87.1% met the WHO's definition of viral suppression, i.e. less than 1 000 copies/ml.

The network for early infant diagnosis HIV PCR laboratories was expanded from nine to eleven facilities during 2020/21. In addition to the existing laboratories, namely Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Chris Hani Baragwanath Academic Hospital, Tshwane Academic Hospital, Groote Schuur, Tygerberg Hospital, INkosi Albert Luthuli Central Hospital (IALCH), Port Elizabeth Provincial Hospital and the Nelson Mandela Academic Hospital, two laboratories (Ngwelezane and Edendale) were added.

For 2020/21, 674 068 HIV PCR tests were conducted (compared to 621 028 in 2019/20), representing an 8.5% increase. Monthly tested volumes varied between 48 807 and 63 051: KwaZulu-Natal processed the highest number of tests with 177 355 (26.3%), followed by Gauteng with 159 912 (23.7%); the Northern Cape processed the lowest number of tests with 9 629 (1.4%). The infection rate decreased from 1.85% in 2019/20 to 1.48% in 2020/21.

Across all laboratories, 4 507 specimens were processed for HIV drug-resistance testing in 2020/21, a 9% decrease from 2019/20. The COVID-19 pandemic may have impacted on annual testing volumes. Three laboratories, CMJAH (37%), IALCH (21%) and Tygerberg (20%) processed the bulk of the testing volumes. CMJAH serves as a backup laboratory for IALCH and Dr George Mukhari, explaining the higher proportion of tests performed at CMJAH.

A total of 11 225 635 National Priority Programme (NPP) tests were conducted in 2020/21, compared to 12 633 912 in 2019/20. This represents an overall decrease of 11%. This was due to the COVID-19 pandemic.

The NIOH plays an important role in supporting government's efforts in occupational health. During the year under review, the NIOH had numerous highlights in the area of occupational health and safety (OHS). The Institute's multidisciplinary teams participated in a significant number of OHS engagements in both the public and private sectors, ranging from partaking in cutting-edge research at a national and global level to supporting innovative programmes to assist vulnerable workers. In the process, the NIOH collaborated with a significant number of key workplace role-players locally, nationally and internationally. This, in turn, contributed to the Institute gaining a new body of knowledge that will enhance and supplement its future efforts to help ensure good OHS in all workplaces.

Several staff members represented the NIOH at key high-level decision-making technical committees, including the National Economic Development and Labour Council (Nedlac), the national DoH and the Department of Employment and Labour (DEL). They also drafted and revised specific occupational health legislation and guidelines – both in the formal and informal economy. In the last quarter of the period under review, organised labour and the national DoH commissioned the NIOH to conduct a nationwide evaluation of occupational health services, focusing on the functioning of OHS committees in the health sector to ensuring that OHS services in the sector are in line with the DEL's Direction on COVID-19. The OHASIS supports surveillance and compliance with occupational and environmental health and safety legislation, and provides information for research. During the period under review, OHASIS has been extensively adapted to cater for new challenges posed by COVID-19. Further enhancements were made to cater for the unique needs posed by the NHLS' laboratory environment. Developments in the improved system included the adaptation of the system to incorporate COVID-19 as a specific disease in the reporting section; the provision of an online screening platform for self-reporting by employees of COVID-19 symptoms and automatic email notifications to an identified health worker; a provision for the presentation of all COVID-19-related information in dashboards; the facility for recording all COVID-19 vaccinations, tests and results; and the capability to capture COVID-19 health care waste. Beyond the NHLS, there has been a keen interest in rollouts of the system by several local and international organisations.

The year 2020 was dominated by the COVID-19 pandemic, which impacted on workplaces across the globe. While the arrival of the pandemic crippled some of the services provided by the NIOH, it provided numerous opportunities that emphasised the value of the Institute well beyond the occupational health space. As employers were legally obligated to conduct COVID-19 risk assessments, the NIOH played a significant role in designing tools to assist workplaces to conduct these assessments and adapted some tools for specific sectors and unique workplaces. These workplace risk assessments highlighted the importance of psychosocial and ergonomic hazards. The majority of stakeholders were capacitated to identify risks and implement requisite control measures to prevent and curb the spread of COVID-19

in workplaces. The NIOH also responded by establishing a dedicated workplace advisory hotline, specifically for occupational health professionals, employees and employers. The hotline has now been expanded to address general workplace queries beyond COVID-19. Queries from the hotline formed the basis for several webinars that catered for various occupational groups across different sectors.

Despite the COVID-19 pandemic and its negative impact on operations, the NHLS' Quality Assurance Department facilitated the accreditation of 15 laboratories during the period under review, compared to 23 in the previous period. At the end of 2020/21, there were 91 accredited NHLS laboratories distributed across all nine provinces in 45 of the 52 metropolitan and district municipalities. Twenty of these laboratories were on the Strengthening Laboratory Management Towards Accreditation (SLMTA) quality improvement programme funded by the US President's Emergency Plan for AIDS Relief (PEPFAR).

In the year under review, the COVID-19 pandemic had a negative impact on the sale of antivenom for the South African Vaccine Producers, a subsidiary of the NHLS. While the SAVP was, for the most part, able to continue within normal parameters, it experienced many challenges. The sale of antivenom for the financial year under review was 13.75% lower than the previous year. The decline in sales can be attributed to delays in receiving important raw materials due to the international flight restrictions imposed by the COVID-19 pandemic. However, the supply of boomslang antivenom increased by 46%.

The year ahead

Organisations such as the NHLS have spent much of the past 14 months scrambling to adapt to extraordinary circumstances. While the fight against the COVID-19 pandemic is not yet won, South Africa, through its mass vaccination programme, strives to reach the required population immunity, thanks to the availability of vaccines. With the population reaching the required immunity, we expect 2021 to be a year of transition. The new normal is going to be different and will not mean going back to the conditions that prevailed in 2019.

Acknowledgements

In conclusion, I would like to thank the Chairperson and the Board of the NHLS for their continued support towards building a strong and stable organisation. None of the achievements of this past year would have been possible without our executive management and staff. For this reason, I would like to thank the NHLS staff for their hard work, passion and commitment to the organisation. Finally, I would like to convey my gratitude to the Board for their oversight and assuring support in the last year.

Dr Kamy Chetty
Chief Executive Officer

1.5 BOARD MEMBERS

Prof Eric Buch
Chairperson

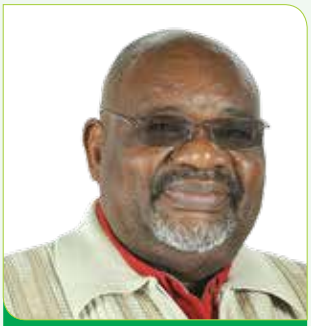
Prof Jeffrey Mphahlele
Vice-Chairperson

Dr Kamy Chetty
Chief Executive Officer

Ms Sphiwe Mayinga

Mr Ian van der Merwe

Mr Michael Sachs



Prof Thanyani Mariba

Prof Mary Ross

Dr Naledzani Ramalivhana

Mr Ben Durham

Prof Mpho Klass Kgomo

Dr Lesley Bamford

Mr Koena Nkoko

Dr Siseko Martin

Dr Balekile Mzangwa

Mr Jonathan Mallett

Dr Gerhard Goosen

Mrs Nicolene Van Westhuizen

Mr Michael Shingange

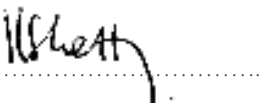
1.6 STATEMENT OF RESPONSIBILITY AND CONFIRMATION OF ACCURACY OF NATIONAL HEALTH LABORATORY SERVICE ANNUAL REPORT

To the best of our knowledge and belief, we confirm the following:

- All information and amounts disclosed in the NHLS' annual report are consistent with the annual financial statements audited by Nexia SAB&T.
- The annual report is complete, accurate and free from any omissions.
- The annual report was prepared in accordance with the Annual Report Guidelines as issued by National Treasury.
- The annual financial statements (Part E) were prepared in accordance with the Standards of Generally Recognised Accounting Practice (GRAP), as applicable to the NHLS.
- The Accounting Authority is responsible for the preparation of the annual financial statements and for the judgements made in this information.
- The Accounting Authority is responsible for establishing and implementing a system of internal control, designed to provide reasonable assurance as to the integrity and reliability of the performance information, the human resources information and the annual financial statements.
- The external auditors are engaged to express an independent opinion on the annual financial statements.

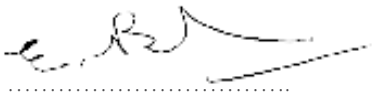
In our opinion, the NHLS' annual report fairly reflects the operations, performance information, human resources information and financial affairs of the NHLS for the financial year that ended on 31 March 2021.

Yours faithfully



Dr Kamy Chetty

Chief Executive Officer



Prof Eric Buch

Chairperson of the Board

1.7 OVERVIEW

About the National Health Laboratory Service

The National Health Laboratory Service is a national public entity, established in terms of the National Health Laboratory Service Act, Act No. 37 of 2000, to provide quality, affordable and sustainable health laboratory services, education and research. It has approximately 268 laboratories across the nine provinces of South Africa, excluding depots, and serves approximately 80% of the South African population.

The NHLS is the main provider of pathology services to the national, provincial and local departments of health, through its countrywide network of quality-assured diagnostic laboratories. It also provides surveillance support for communicable diseases, occupational health and cancer.

The NHLS is managed according to the provisions of the National Health Laboratory Service Act, the NHLS Rules, gazetted in July 2007, and the Public Finance Management Act (PFMA), Act No. 1 of 1999. It is a state-owned enterprise (SOE), governed by a Board and a Chief Executive Officer (CEO).

It has a clear organisational structure, consisting of a head office in Sandringham, Johannesburg, six regions (Limpopo and Mpumalanga, KwaZulu-Natal, Eastern Cape, Western and Northern Cape, Free State and North West, and Gauteng) and two institutes: the NICD, incorporating the National Cancer Registry (NCR) and the NIOH. The six regions are purposefully designed to ensure that the NHLS plans, agrees on budgets and monitors laboratory services jointly with provincial health partners, with the intention for laboratory services to be clearly part of the public health delivery system.

The NHLS delivers services throughout the public sector, from academic, provincial tertiary, regional and district hospitals to primary healthcare facilities. The level of complexity and sophistication of services increases from the peripheral laboratories to the central urban laboratories (with specialised surveillance infrastructure existing at specific sites).

The SAVP, a wholly owned subsidiary of the NHLS, is the only South African manufacturer of antivenom for the treatment of snake, scorpion and spider envenomation.

The National Health Laboratory Service way

Vision

To provide high-quality pathology and laboratory services that are clinically efficient and cost-effective.

Mission

To provide pathology and laboratory services through competent professionals and state-of-the-art technology, supported by evidence-based research, training and innovation to enhance integrated service delivery to meet the needs of the population.

Values

The following values form the guiding principles that govern and align the behaviour of all NHLS employees:

	Value	Description
1.	Care	The primary goal of the NHLS is to ensure the overall care and wellbeing of patients by supporting a strong and effective public healthcare system.
2.	Unity of purpose, shared vision and teamwork	All employees should be united by a common vision and support each other to contribute to a beneficial and safe working environment.
3.	Service excellence	This represents being committed to working with customers and building good relationships with them by understanding their needs, responding quickly and providing appropriate solutions.
4.	Transformation	We will invest in the professional growth of staff by sharing knowledge and experience, peer networking, education through training and seeking opportunities to develop.
5.	Innovation	We are committed to fostering an environment that supports research, with particular emphasis on innovative approaches to diagnostics, surveillance and the strengthening of health systems to support national programmes.
6.	Integrity	We will set and achieve goals, consistently delivering business results, while complying with standards and meeting deadlines.
7.	Continuous improvement	The constant drive of process improvement is the key to a successful organisation. The NHLS needs to create a culture of continuous improvement by empowering all team members within the organisation to continuously seek opportunities for improvement.

1.8 LEGISLATIVE AND OTHER MANDATES

The legislative mandate of the NHLS is derived from the Constitution, the National Health Act, Act No. 61 of 2003 (NHA), the NHLS Act, Act No. 37 of 2000, and several laws, regulations and policies issued by Parliament.

1.8.1 Legislative and other mandates

In terms of the constitutional provisions, the NHLS is, among others, guided by the following sections and schedules:

1. The Constitution of the Republic of South Africa, 1996, places obligations on the state to progressively realise socioeconomic rights, including access to healthcare.
2. Section 27 of the Constitution states the following with regard to healthcare, food, water and social security:
   a) Everyone has the right to have access to:
      (i) Healthcare services, including reproductive healthcare;
      (ii) Sufficient food and water; and
      (iii) Social security, including appropriate social assistance in instances where they are unable to support themselves and their dependents.
3. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
4. No one may be refused emergency medical treatment.

1.8.2 The National Health Act, Act No. 61 of 2003

This Act provides a framework for a structured and uniform health system within South Africa, taking cognisance of the obligations imposed by the Constitution and other laws on national, provincial and local governments regarding health services.

The objectives of the NHA are to do the following:

- Unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa.
- Provide for a system of cooperative governance and management of health services, within national guidelines, norms and standards, to guide each province, municipality and health district to address questions of health policy and the delivery of quality healthcare services.
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research, and a spirit of enquiry and advocacy, which encourages participation.
- Promote a spirit of cooperation and shared responsibility among public and private health professionals and providers, and other relevant sectors within the context of national, provincial and district health plans.
- Create a foundation for the healthcare system which must be interpreted and implemented alongside other laws and policies that relate to health.

1.8.3 The National Health Laboratory Service Act, Act No. 37 of 2000

This Act mandates the NHLS to provide cost-effective and efficient health laboratory services to all public-sector healthcare providers, any other government institution inside and outside of South Africa that may require such services, and any private healthcare provider that requests such services. The Act also mandates the NHLS to support health research and provide training for health science education.

1.8. 4 Additional governance prescripts

The NHLS is required to comply, inter alia, with the following additional prescripts that form part of its governance context:

- Constitution of the Republic of South Africa, Act No. 108 of 1996 (as amended)
- Public Finance Management Act, Act No. 1 of 1999 (as amended)
- National Health Laboratory Service Act, Act No. 37 of 2000
- National Health Act, Act No. 61 of 2003
- Preferential Procurement Framework Act, Act No. 5 of 2000
- Companies Act, Act No. 71 of 2008
- General rules established in terms of section 27 of the NHLS Act
- Protocol on Good Governance in the Public Sector
- King IV Code of Corporate Governance
- Treasury Regulations issued in terms of the PFMA
- All laws that are applicable to the health sector

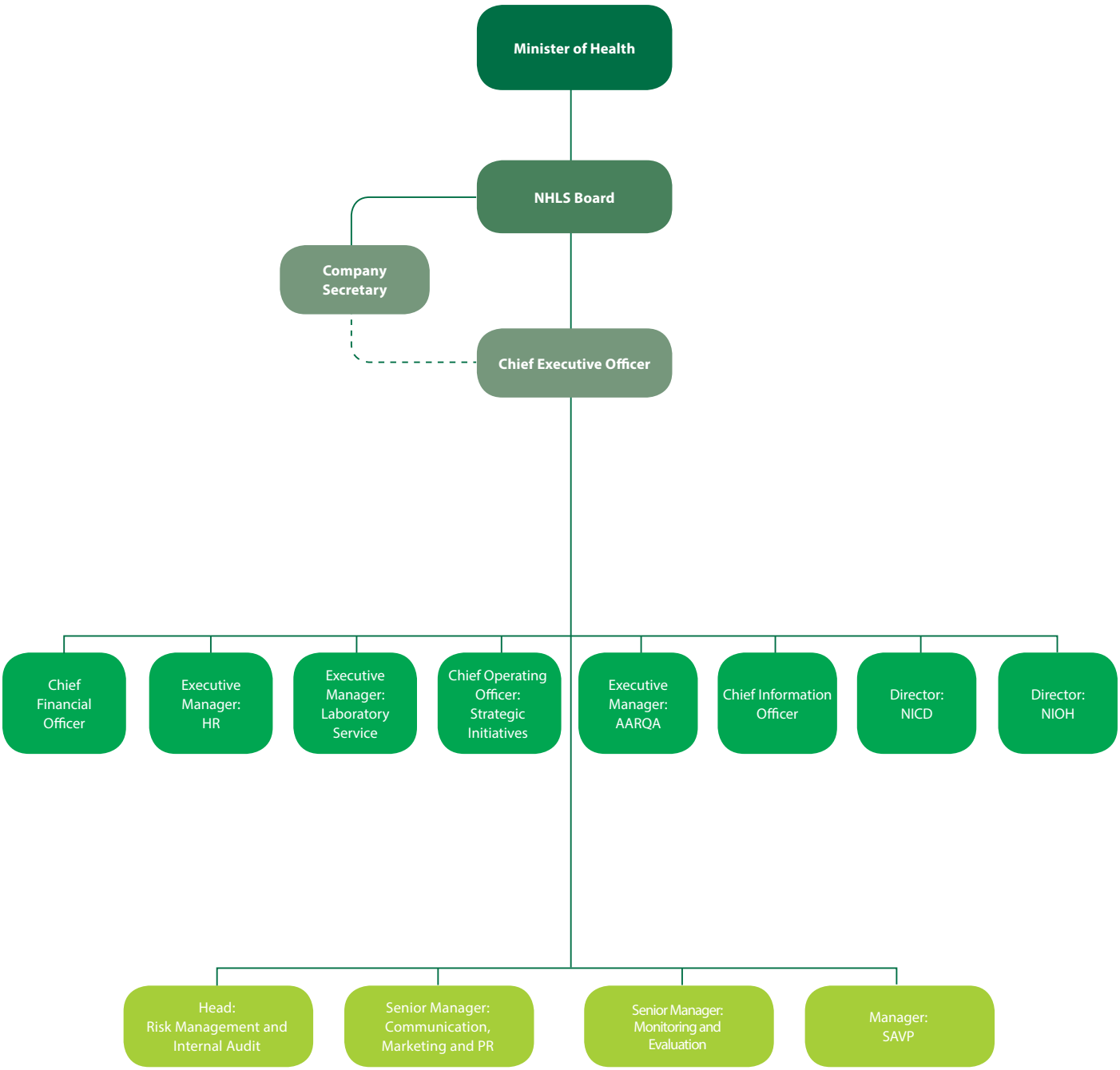
1.8. 5 Policy initiatives

As articulated in its Strategic Plan 2020–2025, the NHLS is committed to support the following:

- The National Health Insurance, which will cover a defined repertoire of pathology services that are aligned with the package of services required per level of care. The pathology services will be delivered at public healthcare level, as well as at higher levels of care as defined by the NHLS Act and in line with the National Health Act. The latter requires the establishment, monitoring and enforcing of quality control standards applicable to pathology services to ensure patient safety.
- The National Public Health Institute of South Africa (NAPHISA), which has the following functions:
  - Communicable diseases
  - The National Cancer Registry
  - Occupational health
  - Non-communicable diseases
  - Injury and violence prevention

The various departments that form part of NAPHISA are still being determined, but it is anticipated that the NICD, including the NCR and the NIOH, will be incorporated into NAPHISA.

1.9 ORGANISATIONAL STRUCTURE



PART B
PERFORMANCE INFORMATION

2.1 AUDITOR'S REPORT ON PREDETERMINED OBJECTIVES

The independent auditor performed the necessary audit procedure on the performance information of the NHLS to provide reasonable assurance in the form of an audit conclusion. The audit conclusion on the performance of the NHLS against its predetermined objectives is included in the report to management, with material findings being reported under the Report on the audit of the annual performance report section of the Auditor's Report on pages 152 to 157.

2.2 SITUATIONAL ANALYSIS

2.2.1 External environment analysis

2.2.1.1 The role of pathology and laboratory service in health care

Pathology and laboratory information enables physicians and other healthcare professionals to make appropriate, evidence-based, diagnostic or therapeutic decisions for their patients. Clinical laboratory services have a direct impact on many aspects of patient care, including, but not limited to, length of stay, patient safety, resource utilisation and customer satisfaction. The NHLS is responsible for most of the HIV and TB tests in the public health system, and plays a critical role in screening for cervical cancer. HIV and TB treatment depends on accurate and timely tests. A unique feature of the NHLS is that all its laboratories are linked using a single laboratory information system. All the data is stored in a central data warehouse, which is a national resource for programme design management, monitoring and evaluation.

2.2.2 Population

South Africa's population is growing rapidly, with recent figures suggesting that 58.8 million individuals currently require healthcare, compared to 55.5 million in the 2017 mid-year population estimates. Gauteng continues to record the largest share of South Africa's population, with approximately 15.2 million people (25.8%) living in the province. The second-largest population of approximately 11.3 million people was recorded in KwaZulu-Natal. Northern Cape maintained its status as the province with the smallest population in the country, with an estimated population of 1.26 million people. The rapid growth in population and increased demand for health means NHLS is required to perform its work to meet this increasing demand.

Table 1: Mid-year population estimates by province, 2019 (STATS SA)

	Population estimate	% of total population
Eastern Cape	6 712 276	11.4
Free State	2 887 465	4.9
Gauteng	15 176 116	25.8
KwaZulu-Natal	11 289 086	19.2
Limpopo	5 982 584	10.2
Mpumalanga	4 592 187	7.8
Northern Cape	1 263 875	2.2
North West	4 027 160	6.9
Western Cape	6 844 272	11.6
Total	**58 775 022**	**100.0**

2.2.3 Burden of disease

2.2.3.1 Communicable diseases

The National Development Plan (NDP) has called for South Africa to achieve a "generation free of HIV AIDS", while Goal 3 of the Sustainable Development Goals (SDG) has set the target to "end the epidemic of AIDS, TB, and malaria" by 2030.

The estimated overall HIV prevalence rate is approximately 13.5% among the South African population. The total number of people living with HIV (PLWHIV) was estimated at approximately 7.97 million in 2019. For adults aged 15 to 49 years, an estimated 19.07% of the population is HIV positive.

The number of AIDS-related deaths would need to reduce by 41% (from 115 167 in 2018 to 68.301 by 2024 and 21 436 by 2030) for South Africa to reach its target of ending the HIV epidemic by 2030.

The 90-90-90 strategy aims to reduce premature mortality and onward transmission of AIDS. The country is driving interventions to ensure that, by 2020, 90% of all people with HIV will know their status, 90% of those who know their status and are HIV positive are put on treatment and 90% of those on antiretroviral treatment are virally suppressed, and by 2024/25, the targets are 95% for each cascade. South Africa is currently at 91-68-83 in terms of performance against 90-90-90. The coverage varies and is 94-72-85 for women, compared to 89-62-80 for men, and 77-60-62 for children. The reach is particularly poor among men and children younger than 15 years.

TB remains the leading cause of mortality in South Africa, despite an almost 25% reduction over three years (39 695 deaths in 2014 to 29 513 in 2016). Improvements in case detection and retaining patients in care will be essential to reduce premature mortality, and to prevent multidrug-resistant (MDR) and extensively drug-resistnt (XDR)-TB. The global End TB strategy has called on WHO member states to reduce the number of deaths caused by TB by 75% by 2025, and 90% by 2030 when compared to 2015 baselines. This translates to a target of not more than 8 510 deaths by 2025, and 3 404 by 2030, to ensure that South Africa achieves its SDG target of "ending the TB epidemic by 2030". This will require the health system to intensify case finding, and placing those diagnosed on treatment, and to ensure that they successfully complete their treatment because TB is curable.

The rapid acceleration plan for HIV and TB treatment access will have a knock-on effect on the NHLS in that it will require significant programme review aimed at the automation, modernisation, consolidation and integration of laboratory platforms and services to ensure affordability.

2.2.3.2 Non-communicable disease

A non-communicable disease (NCD) is medical condition of disease, which by definition is non-infectious and cannot be passed from person to person. NCDs may be chronic diseases for long duration and slow progression, or they may result in more rapid death. According to the WHO, the four main types of NCDs are cardiovascular diseases (like strokes and heart attacks), cancer, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes.

A wave of non-communicable diseases is likely to add further requirements to laboratory services with cancer predicted to increase by at least 30% by 2030 with annual figures reaching an estimated 10 million cases (Lancet, 2017). In a recent survey in rural South Africa, high rates of stroke, cardiovascular disease, hypertension and dyslipidemia were noted in addition to HIV, with at least 56% of individuals having two or more of these diseases (Hofman,2014: SAMJ). By 2030, it is predicted that non-communicable diseases will account for five times as many deaths as communicable diseases in low- and middle-income countries (Hofman, 2014: SAMJ).

2.2.3.3 Causes of death in South Africa

There were 456 612 deaths recorded in 2016; of which 52.7% were females and 47.3 were males. Most deaths occurred in Gauteng, followed by KwaZulu-Natal and the Eastern Cape.

Figure1: Causes of deaths 1997-2016

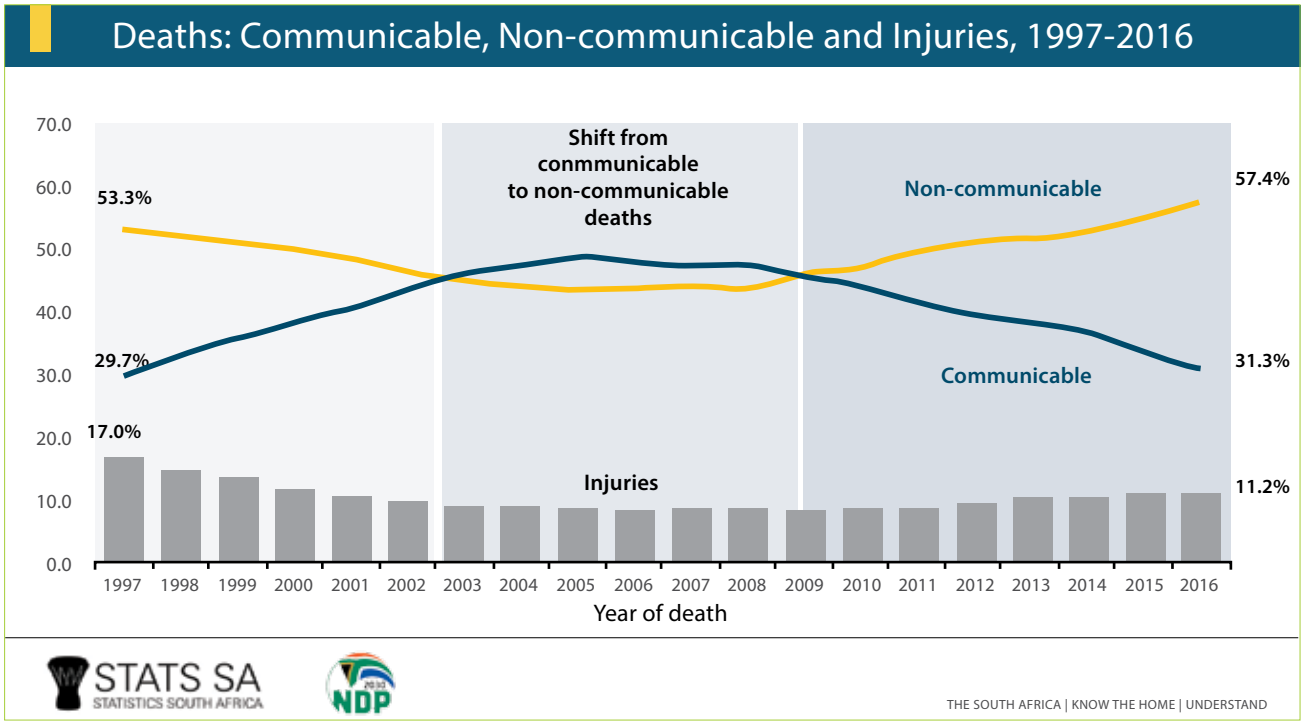
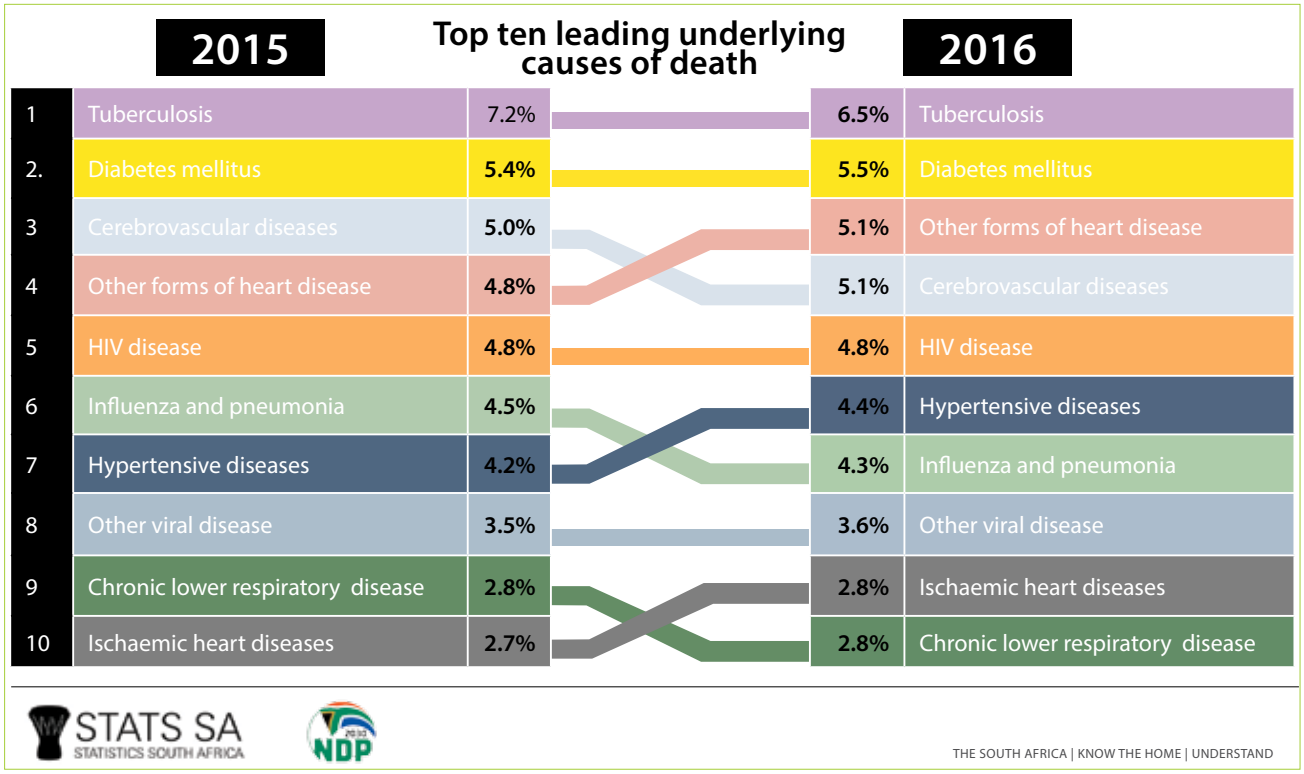


Figure 2: Top ten leading underlying causes of death 2015 vs. 2016



TB remained the number one cause of death in 2016. There is an indication that NCDs are now taking over as the major causes of death in South Africa; with diabetes, various forms of heart diseases and cerebrovascular diseases (strokes) taking a lead.

The NHLS will, therefore, strengthen its services in the diagnosis of these diseases and ensure that it provides rapid and reliable results at affordable prices to support the National DoH in the detection, screening and treatment of these diseases.

2.2.4 Comparison of private and public market in pathology: South Africa

Medical testing laboratories are distributed across the public and private health sector in South Africa. To be able to come up with strategies to prepare for the implementation of the NHI, it is important to compare the staffing, expenditure and test volumes of the private pathology practices and the NHLS. Consideration was given to the NHLS' expenditure data and the health sector data that was reported by the Competition Commission Market Inquiry (CCMI) to analyse differences in pathology provision. The National Pathology Group (NPG) is a specialist subgroup of the South African Medical Association (SAMA) that represents pathologists. The three main private pathology practices within the NPG are Pathcare, Lancet and Ampath, followed by smaller practices. The NPG reported in its submission to the CCMI that approximately 200 000 tests are performed daily by the private laboratory groups. This was extrapolated to 53 million to determine the number of tests done annually. The annual expenditure for private pathology groups was obtained through the Council of Medical Schemes Report. The annual expenditure, as reported by CCMI, was divided by the estimated number of tests to determine a crude average expenditure per test.

There are approximately 91 million tests performed in the public sector compared to 53 million in the private sector. When comparing annual test volumes, the average expenditure per test was approximately R78 and R154 for the public and private sector respectively. Using the population estimates of Statistics South Africa (STATS SA), the per capita (pc) expenditure for the public sector was approximately R153 for the public sector compared to R702 for the private sector based on the assumption that 20% of the population (medical aid population) utilise the private sector.

It must be noted that the NHLS average expenditure per test and per capita expenditure is much lower than the private sector, notwithstanding the additional cost of training and research it incurs.

Table 3: Analysis of public and private pathology sector expenditure and staffing.

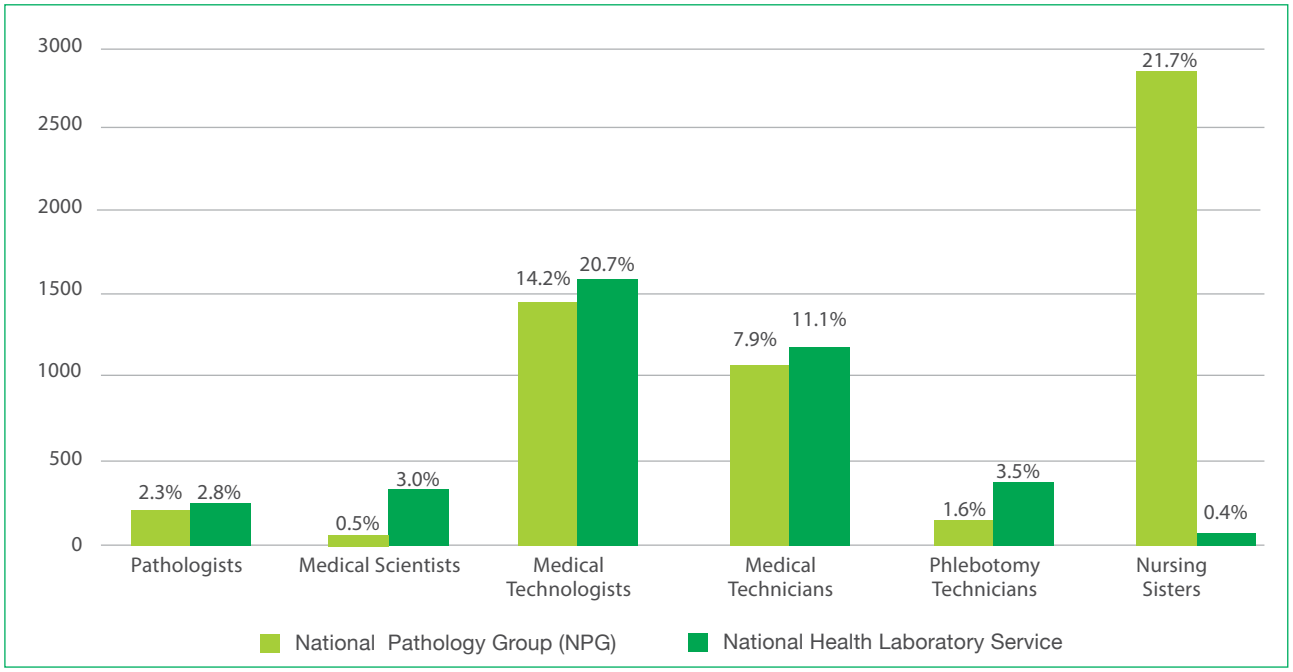
Category	National Health Laboratory Service	National Pathology Group	Total NHLS + Private
Annual test volumes	91 302 409	*53 000 000	144 302 409
Annual expenditure	R7 094 905 000	R8 160 000 000	R15 254 905 000
Average expenditure per/test	**R78	**R154	**R106
Total population	46 499 860	11 624 966	58 124 826
Per capita expenditure	153	702	262
*Annual test volumes extrapolated from data provided to the Competition Commission			

** Calculates as annual expenditure as reported by CCMI divided by annual test volumes extrapolated to the CCMI vs. NHLS annual expenditure divided by NHLS annual test volumes

Staffing distribution in the public and private sector were compared. The majority of the pathology workforce 10 993 (60.5%) are employed within the private pathology sector as opposed to 7 163 (39.5%) in the public sector.

In the financial year under review, the NHLS achieved 72% of the planned training targets compared to the legislated target of 60%. This figure is represented by a training headcount of 5 880 employees who attended technical and non-technical short learning programmes, workshops, seminars, on-the-job training and conferences. This trend is consistent with previous years.

Figure 3: Distribution of key staff categories in the public and private pathology group



2.3 PERFORMANCE INFORMATION BY PROGRAMME

2.3.1 Introduction

Performance information enables the organisation to track how well it is progressing in meeting its planned strategic goals and strategic objectives. The performance information is key to effective management, including planning, budgeting, implementation, monitoring and reporting of information. It also facilitates accountability and enables stakeholders and interested parties to track progress and identify the scope of improvement plans and better understand the issues involved (Framework Performance of Information: National Treasury).

The NHLS achieved 80% of its set targets in 2020/21 financial year. The performance has decreased slightly when compared to the 83% reported in the previous financial year. The NHLS performed well under the pressures presented by COVID-19.

2.3.1.1 Programme 1: Laboratory Service

Programme purpose

This programme represents the core business of the NHLS as mandated by the NHLS Act to provide cost-effective and efficient health laboratory services to all public sector health care providers; any other government institution inside and outside of the South Africa that may require such services; and any private health care provider that requests such services. It is anticipated that the NHLS should provide equitable, comprehensive, quality, timeous and cost-effective pathology service resulting in improved patient care.

Annual Performance Report 2020-2021

Programme 1: Laboratory Service

			Audited/ actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Status	Reason for deviation
Outcome	Output	Output indicator	2018/19	2019/20	2020/21	2020/21			
Clinical effectiveness and efficiency	Modernised laboratory services	Develop and implement a service delivery model	New	New	Service delivery model developed	Service delivery model developed	0	☺	N/A
		Develop and implement the specimen tracking system	New	New	Specimen tracking system developed	Achieved	0	☺	A specimen tracking system called eLABS has been developed and successfully integrated to the NHLS Laboratory Information System. This was tested and implemented in September 2020.
	Improved turnaround times	Percentage of TB microscopy tests performed within 40 hours	94%	95%	95%	96%	1%	☺	The laboratories have seen a drop-in test volume since the COVID-19 pandemic and lockdown. This has resulted in the overachievement of some of the test turnaround times.
		Percentage of TB GeneXpert tests performed within 40 hours	94%	90%	91%	95%	4%	☺	
		Percentage of CD4 tests performed within 40 hours 91%		90%	92%	95%	3%	☺	
		Percentage of HIV Viral Load tests performed within 96 hours	86%	75%	80%	80%	0	☺	N/A
		Percentage of HIV PCR tests performed within 96 hours	76%	85%	85%	83%	-2%	☹	The shortage of consumables in the first and second quarters had a knock-on effect on the turnaround times. The consumables had to be shared between the HIV PCR and COVID-19 testing. This resulted in the demand for consumables far exceeding the supply.

			Audited/ actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Status	Reason for deviation
Outcome	Output	Output indicator	2018/19	2019/20	2020/21	2020/21			
		Percentage of cervical smear screening performed within five weeks	84%	90%	86%	95%	9%	☺	The laboratories have seen a drop-in test volume since the COVID-19 pandemic and lockdown. This has resulted in the overachievement of some of the test turnaround times.
		Percentage of laboratory tests (full blood count) performed within eight hours	95%	90%	92%	96%	4%	☺	
		Percentage of laboratory tests (urea and electrolytes) performed within eight hours	94%	94%	92%	94%	2%	☺	
	Equitable service coverage	Develop and implement point-of-care testing (POCT) plan	New	New	POCT plan developed	POCT plan developed	0	☺	N/A
		Implement digital pathology	New	New	Roll out to 100% anatomical pathology laboratories	0%	-100	☹	The effects of the COVID-19 pandemic contributed to the partial achievement of the target. This project is dependent on increased bandwidth of the MPLS. This tender has been delayed, which impacted on the ability to deliver on digital pathology. A task team has been formed to develop the implementation plan and the budget. The implementation plan and the budget are almost complete.

Linking performance to budget

Programme 1	Budget	Actual Expenditure	(Over)/ Under Expenditure	Budget	Actual Expenditure	(Over)/Under Expenditure
	R'000	R'000	R'000	R'000	R'000	R'000
Laboratory Service	**2020/2021**			**2019/2020**		
TOTAL	7 413 941	7 179 525	234 416	7 648 269*	6 830 737*	817 532*

*Restated

Reasons for deviations from budget

The programme underspend on its budget because all the COVID-19 purchases were done from the corporate cost centre and those expenses are not reflected under the laboratory service budget. In addition, the executive remains cautious and continuously manage labour costs by filling critical posts only.

2.3.1.2 Programme 2: Academic Affairs, Research and Quality Assurance

Purpose of the programme

The main purpose of this programme is to strengthen the mandate of the NHLS of maintaining and providing quality assured and accredited laboratory medicine and the academic platform. Two of the focus areas within this programme are to ensure that research is conducted to contribute to service delivery improvement and quality and to ensure national coverage by NHLS pathologists. The aim is to oversee and collaborate with various training institutions that contribute to the development of qualified and skilled people operating within the scientific field of pathology services.

- **Sub-Programme – Quality Assurance –** The purpose of this sub-programme is to improve Total Quality Management systems within laboratories and support structures to improve the quality of results issued by NHLS laboratories.
- **Sub-Programme – Academic Affairs –** The purpose of this sub-programme is to support and promote training and capacity building of all medical laboratory health professionals to ensure a high-quality technical skill in pathology for the NHLS and the rest of the country. This mandate strengthens the business case for sustained development of the NHLS through the increased output of highly trained Pathologists, Medical Scientists, Medical Technologists and Medical Technicians.
- **Sub-Programme – Research and Innovation –** The purpose of this sub-programme is to create an enabling research environment to promote multidisciplinary world class research and resultant research outputs for the NHLS to contribute to national and global scientific knowledge. The sub-programme provides support for innovative research initiatives whilst promoting exploration of innovative emerging technologies along with technology transfer that will enhance the capacity of South African research and development for novel ideas.

Programme 2: Academic Affairs, Research and Quality Assurance

			Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Status	Reason for deviation
Outcome	Output	Output indicators	2018/19	2019/20	2020/21	2020/21			
High-quality services	Strengthened total quality management systems	Percentage compliance achieved by laboratories during annual quality compliance audits	85%	90%	91%	100%	9%	☺	134 laboratories were audited in the year under review and all 134 laboratories achieved a score above 80%. The reason for over performance is due to an improved implementation of the quality management systems.
		Percentage of laboratories achieving proficiency testing scheme performance standards of 80%	96%	90%	95%	99%	4%	☺	Over-performance was due to the maintenance of good laboratory practice.
		Number of national central laboratories that are SANAS-accredited	50	53	53	51	-2	☹	Efforts to prepare the laboratories for accreditation were disrupted by increased absenteeism due to COVID-19 infections. Social distancing restrictions also led to the suspension of internal audits to assess laboratories' readiness for accreditation. SANAS also suspended the assessment laboratories due to COVID-19 lockdown restrictions.
		Number of provincial tertiary laboratories that are SANAS-accredited	12	13	14	13	-1	☹	
		Number of Regional laboratories that are SANAS accredited	17	12	21	29	8	☺	Most of the laboratories had been assessed in the previous financial year (2019/20). However, the outcomes and certificates were only received in the financial year under review (2020/21).
		Number of District laboratories that are SANAS accredited	11	10	21	35	11	☺	

			Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Status	Reason for deviation
Outcome	Output	Output indicators	2018/19	2019/20	2020/21	2020/21			
		Number of ISO 9001 certified departments	3 departments	3 departments	4 departments	3 departments	-1 departments	☹	The companies suspended assessments due to CPVID-19 restrictions. Social distance restrictions also led to suspension of internal audits to assess departments readiness to assessment.
		Develop and implement the pathologists' national coverage plan	New	New	Approved pathologists' national coverage plan	The pathologists' national coverage plan approved	0	☺	N/A
	Cutting-edge health research	Number of articles published in peer- reviewed journals	593	600	620	673	53	☺	The increased number of publications was due to increased COVID-19 research outputs.
Clinical effectiveness and efficiency	Appropriately trained human resources in adequate numbers	Number of pathology registrars admitted and trained in the NHLS	57	30	30	46	16	☺	There were more funds allocated for registrar posts.
		Number of intern medical scientists admitted and trained in the NHLS	36	50	50	55	5	☺	There were more funds allocated for intern medical scientists posts. Intern medical scientists were required for COVID-19 testing.

Linking performance with budget

Programme 2	Budget	Actual Expenditure	(Over)/ Under Expenditure	Budget	Actual Expenditure	(Over)/Under Expenditure
	R'000	R'000	R'000	R'000	R'000	R'000
Academic Affairs, Research and Quality Assurance	**2020/2021**			**2019/2020**		
TOTAL	311 254	185 742	125 512	54 488	88 800	- 34 312

Reasons for deviations from budget

The executive continued to manage very carefully the filling of posts and focused on filling only the critical vacant posts only.

2.3.1.3 Programme 3: Surveillance of Communicable Diseases

Purpose of the programme

The National Institute for Communicable Diseases (NICD), a national public health institute for South Africa, provides reference microbiology, virology, epidemiology, surveillance and public health research to support the government's response to communicable disease threats.

Programme 3: Surveillance of Communicable Diseases

			Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Status	Reason for deviation
Outcome	Output	Output indicator	2018/19	2019/20	2020/21	2020/21			
High-quality services	A robust and efficient communicable disease surveillance system and outbreak response	Percentage of identified prioritised diseases under surveillance	89%	90%	90%	90%	0	☺	N/A
		Percentage of outbreaks responded to within 24 hours after notification	100%	100%	100%	100%	0	☺	N/A
		Percentage of National Institute for Communicable Diseases (NICD) laboratories that are SANAS-accredited	100%	100%	100%	100%	0	☺	N/A
		Annual report of population-based cancer surveillance	1	1	1	1	0	☺	N/A
		Number of National Institute for Communicable Diseases (NICD) laboratories with WHO reference status	7 laboratories with WHO reference status	7 laboratories with WHO reference status	7 laboratories with WHO reference status	7 laboratories	0	☺	N/A
		Number of articles published in peer-reviewed journals	180	130	140	200	60	☺	The increased number of publications was due to increased COVID-19 research outputs.
		Number of field epidemiologists qualified	9	7	7	7	0	☺	N/A

Linking performance with budget

Programme 3	Budget	Actual Expenditure	(Over)/ Under Expenditure	Budget	Actual Expenditure	(Over)/Under Expenditure
	R'000	R'000	R'000	R'000	R'000	R'000
Surveillance of Communicable Diseases	**2020/2021**			**2019/2020**		
TOTAL	418 876	398 525	20 351	418 890*	410 370*	8 520*

Reasons for deviations from budget

The budget for the personal protective equipment (PPE) was not used because all the procurement of PPE was done centrally and supplied to all the departments. This led to underspending on the budget.

2.3.1.4 Programme 4: Occupational and Environmental Health and Safety

Environment in this context refers to the environment that is contaminated through workplace activities or that can be protected from contamination through workplace in interventions. Safety in this context refers to the synergies between occupational health and occupational safety such as in risk assessments, ergonomic assessments, teaching and training and surveillance of occupational diseases and injuries.

Programme Purpose

The National Institute for Occupational Health (NIOH), National Public Health Institute, provides occupational and environmental health and safety support across all sectors of the economy to improve and promote workers' health and safety. National and provincial government departments and public entities are important clients, including the Medical Bureau for Occupational Diseases (MBOD) of the NDoH. The Institute achieves this by:

i) providing occupational medicine, hygiene, advisory, statutory pathology and laboratory services;

ii) conducting research; and

iii) providing teaching and training in occupational and environmental health and safety.

			Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from planned target	Status	Reason for deviation
Outcome	**Output**	**Output indicator**	**2018/19**	**2019/20**	**2020/21**	**2020/21**			
High-quality services	Robust and efficient occupational and environmental health services	Percentage of occupational, and environmental health laboratory tests conducted within the predefined turnaround time	75%	90%	90%	97%	7%	☺	Over-achievement due to increased laboratory efficiency and decreased number of tests conducted by some of the laboratories during the COVID-19 pandemic.
		Number of occupational, environmental health and safety assessments completed	36	30	32	15	-17	☹	A number of workplaces closed down during lockdown. Most assessments were put on hold for longer than anticipated. Workplaces that were still operational could not accommodate our staff due to observing social distancing and adhering to travel restrictions. Many staff members unfortunately had to take leave as they got infected or were affected by COVID-19. However, instead of exposure assessments, staff members involved in risk assessments became more involved in extensive training activities/ webinars that became a priority for workplaces across the country.
		Number of occupational health surveillance reports produced	4	4	4	4	0	☺	N/A
		Percentage of NIOH laboratories that are SANAS-accredited	New	New	100%	100%	0	☺	N/A

Linking performance with budget

Programme 4	Budget	Actual Expenditure	(Over)/ Under Expenditure	Budget	Actual Expenditure	(Over)/Under Expenditure
	R'000	R'000	R'000	R'000	R'000	R'000
Occupational and environmental health and safety	**2020/2021**			**2019/2020**		
TOTAL	156 512	135 843	20 669	156 502*	137 078*	19 424*

Reasons for deviations from budget

The over spend was due to the budget cut by the Department of Health which led to decreased funding.

2.3.1.5 Programme 5: Administration

Programme purpose

The administration programme plays a crucial role in the delivery of the NHLS services through the provision of a range of support services, such as organisational development, HR and labour relations, information technology, property management, security services, legal, communication and the integrated planning function. NHLS depends highly on the effective management of financial resources and procurement process as administered within the financial department. Generating sufficient revenue remains a critical focus area for NHLS to ensure financial viability and sustainability. There are four sub-programmes, namely:

Financial Management

The purpose of this sub programme is to improve cash flow position of NHLS.

Information and Communication Technology (ICT)

The purpose of sub programme is to build a robust and agile ICT infrastructure and innovative digital solutions to facilitate and enable state of the art laboratory service at NHLS by 2022.

Human Resources Management

Purpose of sub-programme is to provide effective services through efficient processes, systems and adequate Human Resources.

Sub-programme: Financial Management

			Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Status	Reason for deviation
Outcome	**Output**	**Output indicator**	**2018/19**	**2019/20**	**2020/21**	**2020/21**			
Cost-effective services	Improve liquidity position of the NHLS	Ratio of current assets to current liabilities	3.1 times	2:1	2:1	3,1:1	1.1	☺	The cash balance has remained consistently high as a result of increased cash collections. The NHLS has successfully demonstrated its ability to pay its current liabilities out of current assets and easily exceeded the standard for this ratio of 2:1.
		Cash flow coverage ratio (operating cash in-flows/ total debt)	4.1 times	1.5:1	2:1	2,9:1	0.9	☺	This is due to the significant reduction of payables from exchange transactions and an increase in cash and cash equivalents.
		Number of creditors' days	29 days	30 days	30 days	35 days	15 days	☹	The NHLS continued to pay all its suppliers timeously.
		Number of debtors' days	127 days	250 days	120 days	109 days	11 days	☺	There have been payments from provinces in lieu of current and prior years' debt. This has assisted in reducing both current and prior debt. Continuous engagements are in place to encourage the payment of outstanding debt.
		Percentage turnaround time for awarding tenders within 90 days.	84%	80%	85%	69%	-16%	☹	It was difficult to convene the various bid evaluation and pricing/B-BBEE committee meetings on a regular basis due to COVID-19 safety protocols observed during the COVID-19 pandemic. The NHLS has since piloted and introduced virtual electronic platforms for bid evaluation that will mitigate the challenges encountered in the period under review.
	Reduced cost of pathology services to clients	Develop and implement revenue and costing strategy.	New	New	Revenue and costing strategy developed	Revenue and costing strategy developed	0	☺	N/A

			Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Status	Reason for deviation
Outcome	**Output**	**Output indicator**	**2018/19**	**2019/20**	**2020/21**	**2020/21**			
Good governance	Audit opinion of the Auditor-General	Clean audit opinion of the Auditor-General	Unqualified	Unqualified	Unqualified	Unqualified	0	☺	N/A
	Corruption-free organisation	Percentage of allegations reported through the NHLS tipoff platform that are investigated within 180 days	New	New	90%	92%	2%	☺	An allegation predication assessment process was introduced, which resulted in the quick completion of reported allegations.

Sub-programme: Information and Communication Technology

			Audited/ actual/planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Status	Reason for deviation
Outcome	**Output**	**Output indicator**	**2018/19**	**2019/20**	**2020/21**	**2020/21**			
Clinical effectiveness and efficiency	Modernised information technology systems	Develop and implement a real-time communication system with patients	New	New	Real-time communication system with patients developed	Real-time communication system with patients developed, and included messages to patients for COVID-19 results	0	☺	N/A
		Implement the interface between the NHLS LIS and the HPRS	New	New	20% implementation of the HPRS	0%	-20%	☹	The NHLS did not interface any clinics because the national DoH did not implement HPRS in any clinic in the 2020/21 financial year. The KPI depends on the implementation of the HPRS by the national DoH.
		Develop and implement the order entry system	New	New	Order entry system developed	Order entry system developed	0	☺	N/A
		Percentage system uptime for critical systems at laboratory level	99%	99%	99%	100%	1%	☺	N/A

Sub-programme: Human Resources

			Audited/ actual/planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Status	Reason for deviation
Outcome	**Output**	**Output indicators**	**2018/19**	**2019/20**	**2020/21**	**2020/21**			
Clinical effectiveness and efficiency	Appropriately trained human resources in adequate numbers	Staff turnover ratio	3%	5%	5%	3%	2%	☺	N/A
		Average staff recruitment turnaround time within 90 days	89%	80%	90%	96%	6%	☺	The over-achievement was due to the emergency recruitment of staff to respond to the COVID-19 pandemic.
		B-BBEE compliance	New	New	Level 6	Not achieved	Not achieved	☹	The audit was delayed by COVID-19 restrictions and also the suspension of the Chief Financial Officer, Head of Department: Supply Chain Management and other procurement officers. The audit is expected to be completed in the 2021/22 financial year.
		Number of intern medical technologists and student medical technicians admitted and trained in the NHLS	248	200	250	251	1	☺	N/A
	Performance-driven workforce	Percentage of employees with approved and evaluated performance agreements	94%	95%	95%	89%	-6	☹	Due to the current pandemic most of NHLS staff were isolated or had to be quarantined, which led to the numbers not being met.

2.3.2 Linking performance with budget

Programme 5	Budget	Actual Expenditure	(Over)/ Under Expenditure	Budget	Actual Expenditure	(Over)/Under Expenditure
	R'000	R'000	R'000	R'000	R'000	R'000
Administration	**2020/2021**			**2019/2020**		
TOTAL	1 357 958	3 880 030	- 2 522 072	1 380 405*	1 167 514*	212 891*

Reasons for deviations from budget

The over expenditure is due to the COVID-19 purchases which was centralised within the corporate office. The supply of goods was very limited during the pandemic as a result it was necessary to centralise procurement of these goods to be able to manage the equitable distribute to the regions.

The budget for 2020/21 was approved pre- COVID pandemic, hence the expenditure was not budgeted for.

2.3.3 Response to the COVID-19 pandemic

On 31 December 2019, the World Health Organisation (WHO)'s China country office was informed of cases of pneumonia of unknown cause detected in Wuhan City, Hubei Province, China. On 7 January 2020, the causative pathogen was identified as a being novel coronavirus (COVID-19). The majority of these cases were linked to a seafood, poultry and live wildlife market in Wuhan City, suggesting that the novel coronavirus had a possible zoonotic origin. The virus initially appeared to spread through importation, followed by community transmission.

COVID-19, which began in December 2019, presented a significant challenge for the entire world. The NHLS, through the NICD, has dealt with outbreaks in the past, and was therefore well prepared to respond in a way that would offer substantial protection to the public.

After the WHO had conducted a risk assessment of the novel coronavirus, the risk for global spread was deemed high. The WHO's regional office for Africa subsequently classified South Africa as Priority 1 country, based on the traffic between China and South Africa, taking account of the International Health Regulations.

The discussions for the preparation of the response to the COVID-19 pandemic started in January 2020, when the NHLS was informed of the outbreak. The planning process was initiated while, at the same time, drafting a preparedness and upscaling plan in consultation with all the relevant stakeholders.

Although no confirmed case of COVID-19 had been reported in South Africa by 19 February 2020, the NICD immediately increased its suspension index and closely monitored the situation and tested patients that satisfied the criteria for suspected cases, bearing in mind that it was influenza season in the northern hemisphere, and respiratory tract infections were common.

South Africa diagnosed its first case of COVID-19 on 5 March 2020. The patient was a 38-year old male from KwaZulu-Natal who had travelled to Italy. The President of the Republic, Mr Cyril Ramaphosa, declared COVID-19 a national state of disaster on 15 March 2020. In his speech, he said, "There are now more than 162 000 people who have tested positive for COVID-19 across the globe. Given the scale and the speed at which the virus is spreading, it is now clear that no country is immune from the disease or will be spared its severe impact". There were 61 confirmed positive cases of COVID-19 in South Africa by the time the President made that announcement. During the initial phase, when there were no imported cases of COVID-19, the testing for SARS COV-2 was done by the NICD. As the number of cases increased, the NHLS rapidly decentralised testing to the NHLS' laboratories. The NHLS started with a testing capacity of ~2 650 tests per day. In preparation for this, the NHLS performed a needs analysis to determine the COVID-19 readiness of its virology laboratories. Literature review and research on COVID-19 was conducted regarding the systems and types of testing that could be done. In terms of the testing methodology, molecular testing (RT-PCR based testing) was recommended as a test for initial diagnosis. The serological tests were complementary at point of care (POC). The review included the types of swabs and transport media to be used for testing. The NHLS capacitated itself through the urgent procurement of state-of-the-art PCR equipment in virology laboratories around the country. The equipment procured included automated or semi-automated extraction instruments, which greatly reduced turnaround time. The procurement of these analysers increased the NHLS' daily testing capacity to approximately 30 000 per day, with approximately 128 laboratories testing for COVID-19.

The initial plan was to ensure diagnostic capacity based on testing patients that fulfil the case definitions. In addition, population surveillance would follow as the testing capacity was upscaled.

In an effort to intensify case finding, the NHLS made use of mobile units to trace contacts and take samples if the suspects met the case definition. The NHLS had seven mobile units, which were distributed .to provinces. In addition, it purchased an additional 60 mobile units. The purpose of procuring these mobile units was to scale up the NHLS' visibility and take specimens in the communities. These would later be converted at the sampling and testing sites in the communities.

The mobile units were used for the tracing and sampling of contacts. They were staffed with a driver and two nurses. The nurses have been trained and are competent to screen and collect samples from patients who meet the case definition. The location and deployment of the mobile units was discussed and agreed upon with the Provincial Departments of Health.

The distribution of the mobile units was based on the number of districts and metros, and also the population size. The intention was for each district in South Africa to at least have a mobile unit. Distribution was allocated so that each district and metro would get one mobile clinic, and each province would get one additional unit, except for Gauteng, which would get four additional units. Three mobile units were kept in reserve at Head Office (Sandringham) to be deployed as needed. The allocation was adjusted based on the changing needs, e.g. hot spots, requests to intensify community screening and testing, etc.

At the same time, an emergency operating centre (EOC) and a call centre for doctors and the community were prepared. The NHLS engaged with the national DoH from the onset of the outbreak. The NHLS participated in all planning, advisory and decision-making committees. For example, it was represented in the National Joint Operating Committee (NatJOC), the Provincial Joint Operating Committees (ProvJOC) in all provinces, the Incident Management Team (IMT), the Ministerial Advisory Committee (MAC) and other relevant committees. The NHLS' CEO updated the Minister of Health by providing regular reports outlining the activities of the NHLS in relation to the COVID-19 outbreak.

Challenges experienced during the pandemic

Whilst the NHLS had the equipment to perform 36,000 tests per day, it has experienced major supply challenges for extraction kits and the high throughput machines. This unavailability of extraction kits was due to an international shortage of the reagents used, which had an impact on the number of extractions that can be placed into the PCR machine.

Whilst the NHLS had procured a number of PCR kits it was limited by the lack of extraction kits. With regard to the high throughput machines, the suppliers were experiencing difficulties with production and high demand and could not keep pace with global needs.

The above challenges led to test backlogs in the laboratories and increased turnaround time of results. This was compounded by unavailability of staff due to COVID-19 infection and COVID-19 lockdown and social distancing regulations.

Mitigation plans

- To mitigate the risks, the NHLS had to diversify its PCR and extraction platforms. It had procured different PCR and extraction platforms.
- The NHLS sourced different suppliers to obtain extraction kits in order to avoid depending on one supplier.
- The NHLS issued an advisory to laboratories, in line with the testing strategy developed with the DoH, to prioritise testing samples for those most at risk.
- The highest priority was those with a medical need and for clinical diagnosis, i.e. suspected symptomatic COVID-19 cases and clinical diagnosis for patients with respiratory disease at health care services.
- The rate of test positivity in the provinces and districts was also reviewed on a daily basis and resources were prioritized, as far as possible, to high positivity hotspots.
- The NHLS decentralised testing to district laboratories and mobile laboratories by using the GeneXpert instruments once the test kits became available. The organisation had 128 COVID-19 testing laboratories, including the mobile laboratories, by the end of the 2020/21 financial year.
- It was able to refer work to private and academic laboratories when the need arose.
- The implementation of SARS-CoV-2 antigen rapid testing also played a vital role in alleviating pressure from the laboratories.

Despite the COVID-19 pandemic and its negative impact on operations, the NHLS managed to conduct over 4 miillion COVID-19 tests by the end of the financial year with an avarage turnaround time of 48 hours.

2.4 BUSINESS UNIT PERFORMANCE

The NHLS has five business units that serve to execute its core mandate, which has the following main objectives:

- support the Department of Health (DoH) in delivering laboratory services to South Africans;
- provide training in health sciences in partnership with universities and universities of technology; and
- promote and undertake relevant and innovative health-related research.

The business units are as follows:

- Laboratory Service, which is further classified into six regions: Eastern Cape, Free State and North West, Gauteng, KwaZulu-Natal, Limpopo and Mpumalanga, Western and Northern Cape;
- Academic Affairs, Research and Quality Assurance (AARQA);
- National Priority Programmes (NPP);
- National Institute for Communicable Diseases (NICD); and
- National Institute for Occupational Health (NIOH).

In addition, the organisation has the following support services departments:

- Human resources;
- Finance;
- Information and communication technology; and
- Communication, marketing and public relations.

The NHLS also has a subsidiary, South African Vaccine Producers (SAVP).

2.4.1 Laboratory Service

Tabita Makula
Eastern Cape

Jone Mofokeng
Free State and North West

Bahule Motlonye
Gauteng

Sibulele Bandezi
KwaZulu-Natal

Jacob Lebudi
Limpopo and Mpumalanga

Nasima Mahomed
Northern and Western Cape

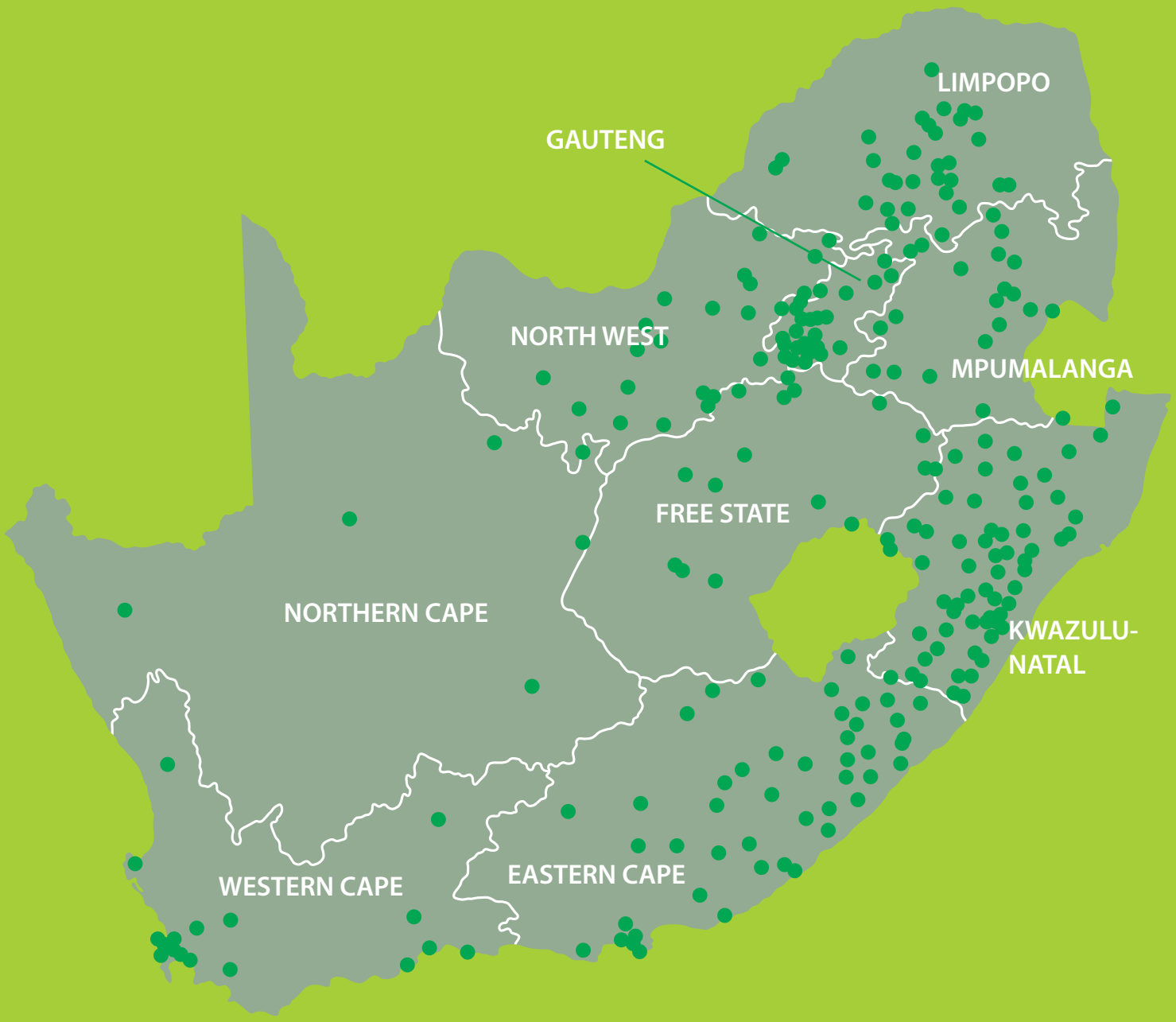
Introduction

The NHLS is mandated to perform three functions: diagnostic services, research and training. This section focuses on the diagnostic services that are provided across South Africa through laboratory services. The NHLS operates in all nine provinces and is divided into the following regions: Eastern Cape, Free State and North West, Gauteng, KwaZulu-Natal, Limpopo and Mpumalanga, and Northern and Western Cape. Each region provides services across all South Africa's districts. In some regions, like Gauteng, services are also provided to other regions and countries.

The NHLS has at least one laboratory in every district across the country, from the most rural and least populated areas in the Northern Cape to the metropolitan municipalities in Gauteng, KwaZulu-Natal and the Western Cape. Where hospitals and primary health clinics do not have an on-site laboratory, specimens are sent to the nearest laboratory via courier once or twice a day. Depots receive specimens, register them and refer them to the laboratories.

The NHLS' national footprint

Figure 1.1: Map of South Africa showing all the laboratories in the provinces



Laboratory Service - Diagnostic services and new developments

Test volumes

A total of 92 471 586 tests were performed in 2020/21. This is a decrease of approximately 5.2% compared to 2019/20. The decrease in the number of tests conducted was due to the nationwide lockdown restrictions imposed due to the COVID-19 pandemic.

Total tests done per province

Province	Current Year	Previous Year
	Sum of Ytd Vol	
Western Cape	10784584	11687593
Eastern Cape	9435688	10382009
Free State	4592831	4534011
Northern Cape	1735838	1753145
Gauteng	26105047	27067097
North West	4974780	4848203
Limpopo	5709329	6154102
Mpumalanga	5274906	5174169
KwaZulu-Natal	23858583	25939793
GRAND TOTAL	**92 471 586**	**97 540 122**

National Priority Programme tests

The NHLS' laboratories support the Department of Health's National Priority Programmes (NPP) by testing for tuberculosis, cervical screening, and HIV and AIDS. Each province supports this programme where facilities permit and a demand is present. A total of 11 225 635 NPP tests were conducted in 2020/21, compared to 12 633 912 in 2019/20. This represents an overall decrease of 11%. The decrease in test volumes was due to the COVID-19 pandemic. Having said that, figures 1.2 to 1.6 below indicate that the HIV PCR (Figure 1.2) and HIV viral load tests (Figure 1.3) showed a slight increase compared to the same period in 2019/20. Tests for CD4 (Figure 1.4), the TB GeneXpert (Figure 1.5) and cervical smears (Figure 1.6) showed a general decrease in volume.

HIV/AIDS test volumes by province

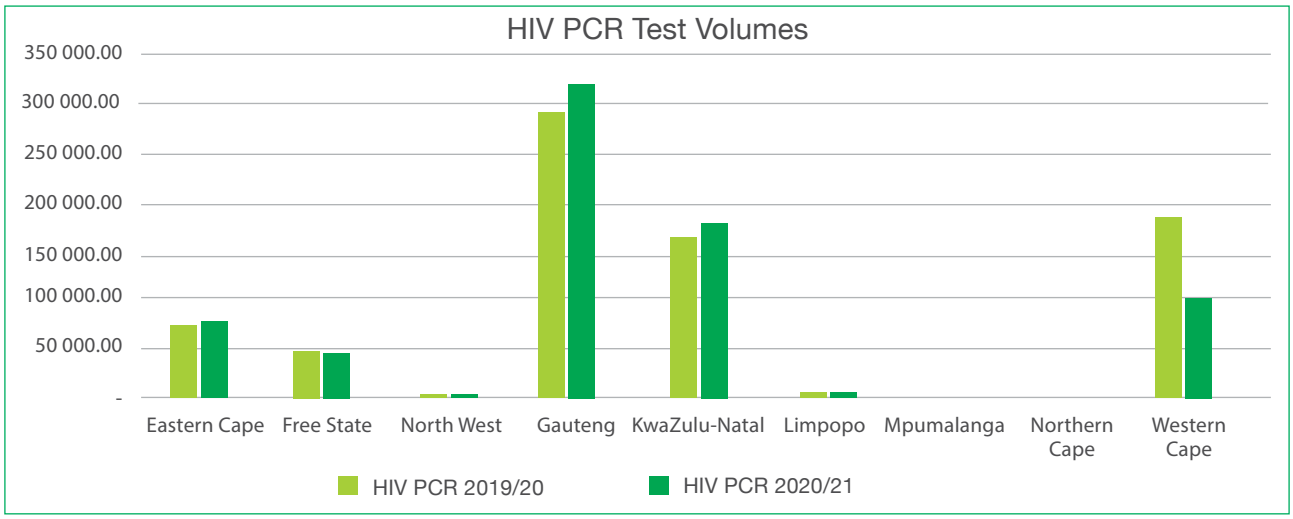
Province	Test done FY2020/21
Eastern Cape	938 734
Free State	458 354
Gauteng	2 265 125
KwaZulu-Natal	2 692 743
Limpopo	624 708
Mpumalanga	867 231
Northern Cape	137 646
North West	539 453
Western Cape	550 740

HIV/AIDS testing includes CD4 count, diagnosis of HIV through Polymerase Chain Reaction (PCR) tests and viral load tests.

TB test volumes by province

Province	Test done FY2020/21
Eastern Cape	362 753
Free State	69 394
Gauteng	266 165
KwaZulu-Natal	704 650
Limpopo	97 387
Mpumalanga	99 896
Northern Cape	54 063
North West	90 653
Western Cape	266 493

Figure 1.2: HIV PCR test volumes



* Where there are no test volumes, those tests are referred to other provinces.

Figure 1.3: HIV viral load test volumes

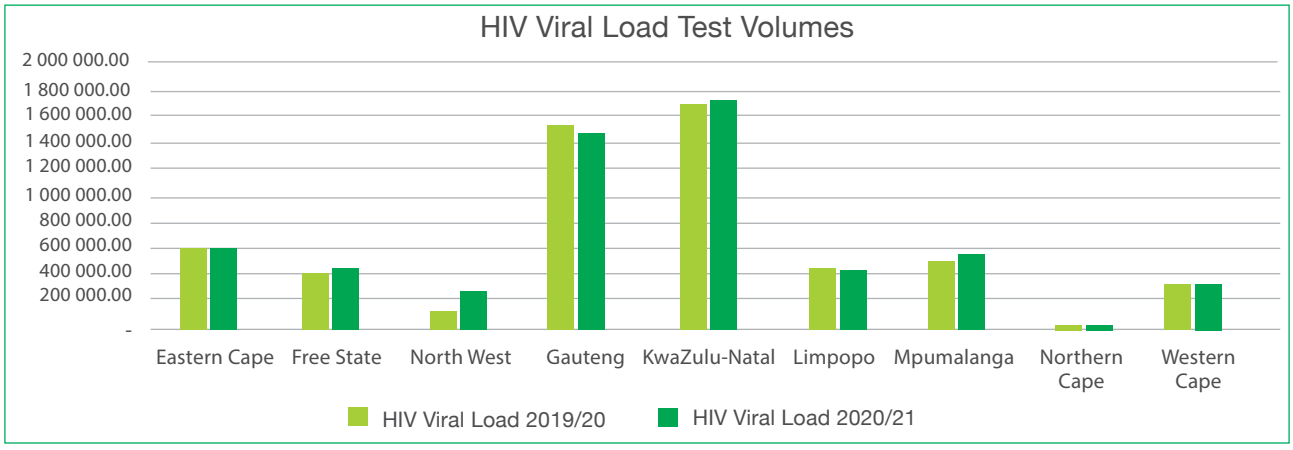


Figure 1.4: CD4 load test volumes

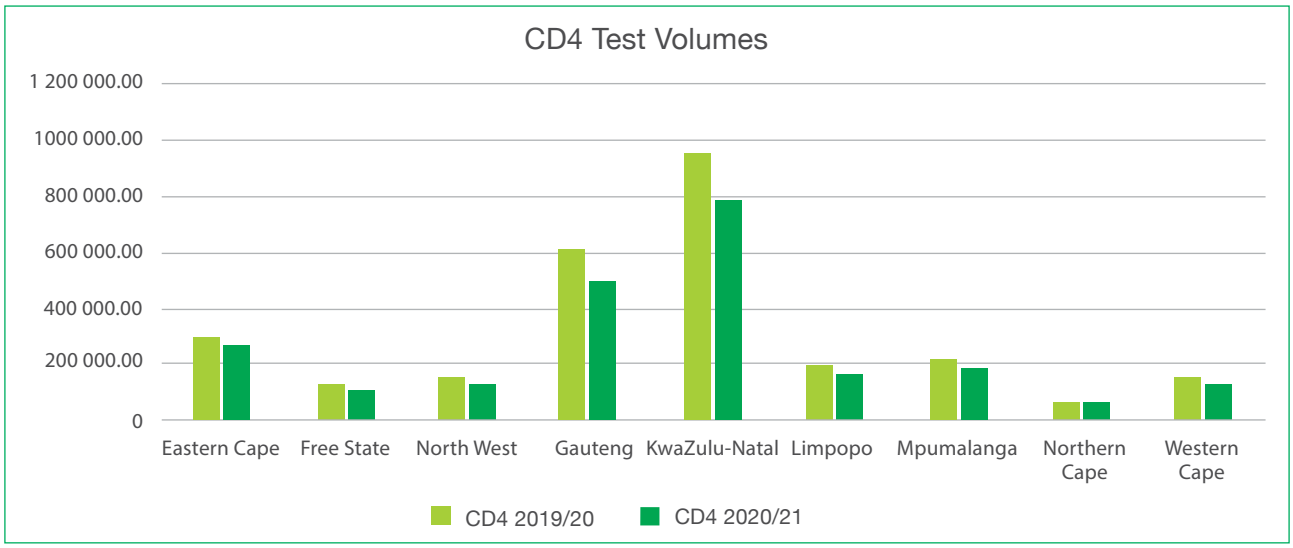


Figure 1.5: Tuberculosis GeneXpert test volumes

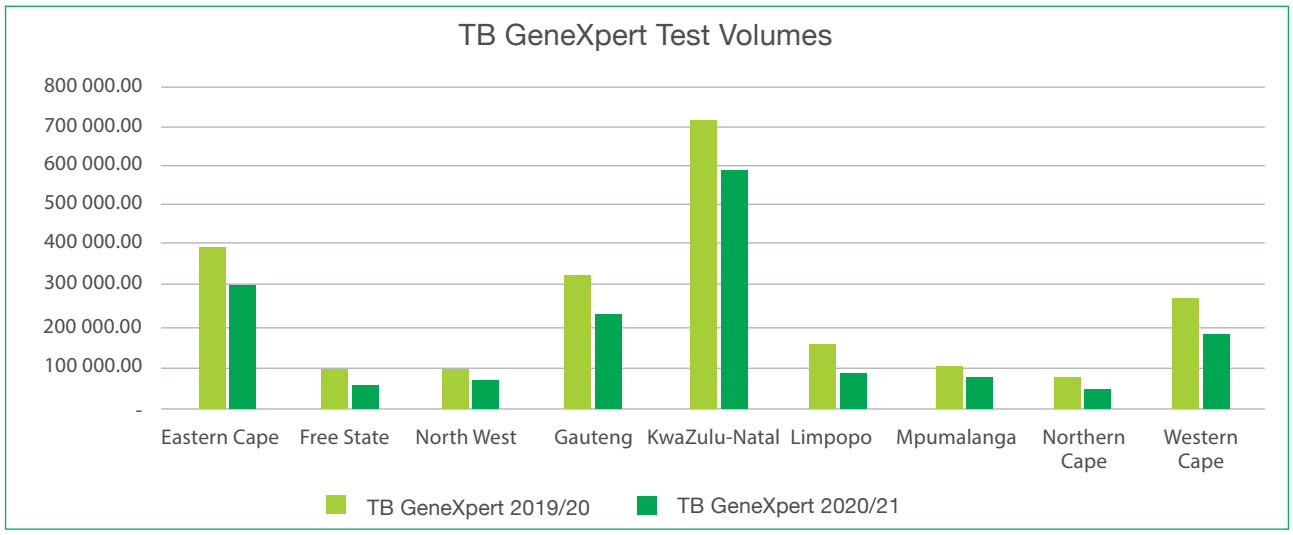


Figure 1.6: Cervical smear test volumes

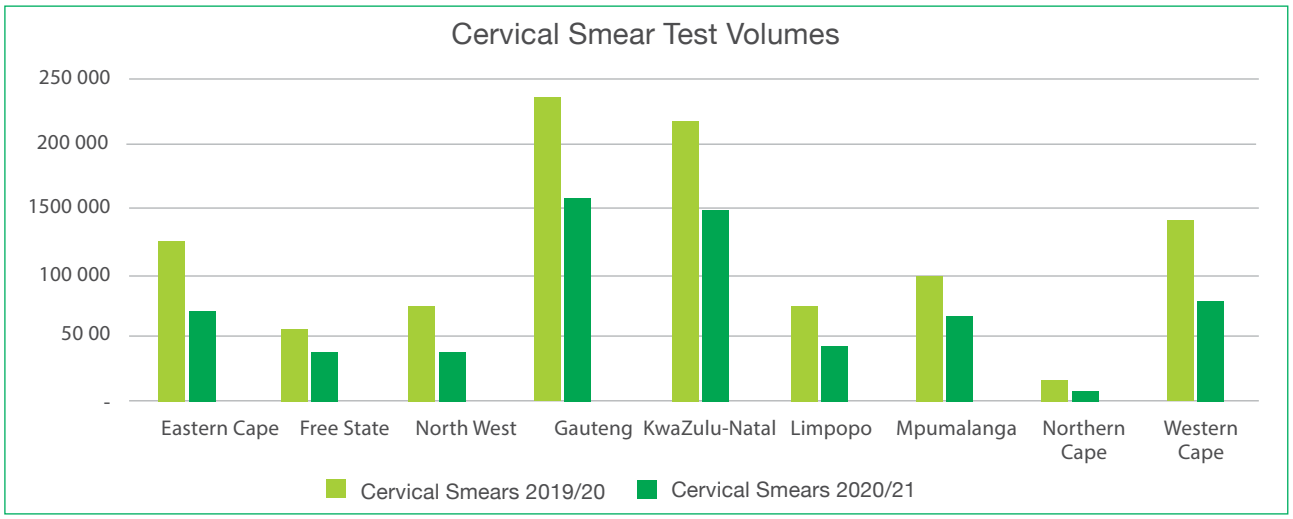


Table 1.2: *New tests across provinces*

Province/ region	Business Unit	Laboratory	New tests added
Eastern Cape	Nelson Mandela Academic Laboratory	Haematology	Protein- C and Protein-S
	Nelson Mandela and Sarah Baartman	TB Laboratory	Bedaquiline
Gauteng	Dr George Mukhari Academic Hospital	Haematology	Lupus anticoagulant Anti-thrombin 3 Protein-C Protein-S AFXa (Anti Factor Xa)
	Tshwane Academic Division	Histology	AFXa (Anti factor Xa) Von Willebrand (antibody and activity) Platelet aggregation
	Dr George Mukhari Academic Hospital	Histology	Anti-adrenocorticotropin Growth hormone Luteinizing hormone Thyroid-stimulating hormone
	Charlotte Maxeke Johannesburg Academic Hospital	Infection Control	Enteric pathogens Meningeal pathogens MRSA detection Atypical pathogen pneumonia Carbapenemase detection
	Charlotte Maxeke Johannesburg Academic Hospital	Chemical Pathology	11 – deoxycortisol Aldosterone
Limpopo	Polokwane	Capricon Lab: Mankweng New	Respiratory syncytial virus CEA, PSA, C199
Western Cape	Groote Schuur Academic / Red Cross Children Hospita	Chemistry Laboratory	Renin, aldosterone, growth hormone, C-peptide and IgF1
	Groote Schuur Academic / Red Cross Children Hospital	Histology Laboratory	BRAF and IDH1
	Groote Schuur Academic / Red Cross Children Hospital	Tissue Immunology Laboratory	Calprotectin test
	Tygerberg Academic Hospital	Chemistry Department	Procalcitonin (PCT) and pro BNP
	Tygerberg Academic Hospital	Haematology	Anti-factor Xa
		Hermanus	Lateral flow assay (LFA)
		Mossel Bay	D'dimer

NB: Refer to page 232 for a comprehensive list of COVID -19 testing facilities

Test turnaround times

The turnaround time of test results is one of the most prominent indicators of laboratory service performance and quality of service, and is often used as a key performance indicator. In the past years, the NHLS has achieved good turnaround times during the analytical phase. It continues to perform well in terms of the timeous delivery of test results.

Table 1.3: *Turnaround times of test results per region*

Region	TB GXP	CD4	HIV VL	HIV PCR	Cervical Smear	FBC	U&E
	Target = 91%	Target = 92%	Target = 80%	Target = 85%	Target = 86%	Target = 92%	Target = 92%
Eastern Cape	93%	95%	76%	72%	94%	93%	94%
Free State / North West	96%	97%	73%	78%	100%	94%	94%
Gauteng	98%	97%	70%	87%	89%	97%	92%
KwaZulu-Natal	92%	95%	86%	80%	98%	95%	95%
Limpopo	98%	93%	93%	**	100%	96%	95%
Western Cape	97%	96%	81%	93%	97%	97%	97%

** test referred outside the region

The NHLS performed generally well in all regions, despite all the COVID-19 lockdown restrictions. Under performance in some of region of the HIV Viral Load Tests (HIV VL) was mainly due to shortage of consumables to perform the test. This challenge was eventually resolved.

Notable achievements

Eastern Cape

The Eastern Cape maintained SANAS accreditation in all the laboratories accredited in the previous year and achieved initial accreditation for the Bisho district laboratory. As SANAS assessments were conducted remotely due to the pandemic, two district laboratories, Victoria and Zitulele, were unable to be assessed due to problematic IT infrastructure. Both laboratories will be assessed in the new financial year.

Bisho laboratory in the Buffalo City and Amathole Business Unit.

Two laboratories were subjected to Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) audits. St Elizabeth Regional laboratory obtained a five-star rating (97.8%) for a second successive year, and Port Alfred laboratory achieved a four-star rating (93.4%), improving from a three-star rating in the previous financial year.

Non-accredited laboratories are subjected to quality compliance audits to assess compliance with the ISO 15189 international standard. The region achieved an overall average of 95% compliance.

Free State

The Botshabelo and Bethlehem laboratories achieved full SANAS accreditation. The Kroonstad and Pelonomi laboratories passed SANAS surveillance and maintained their accreditation status. The Universitas Business Unit maintained its SANAS accreditation for all departments. The Human Genetics Department was assessed in March 2020 and was recommended for SANAS accreditation.

The eLABS sample and turnaround time tracking system was introduced in the laboratories to trace patient specimens collected at clinics and delivered to the laboratory. The success of the project is not yet fully realised, since clinics are not scanning all patient samples as required.

The laboratory was chosen to provide mobile COVID-19 community testing, and is also providing COVID-19 testing at the Caledon, Ficksburg and Van Rooyen border posts.

North West

The eLABS system was linked to selected clinics, and the turnaround time of viral load tests was monitored. This system was rolled out in three of the districts except Dr Ruth Segomotsi Mompati, in accordance with the grant funder's selection. The purpose of this system was to improve courier, laboratory operations and turnaround time so as to continue to support the Phuthuma Project among the districts.

The liquid-based cytology collection methodology in the province reached 100% rollout through the cooperation of facilities.

The NHLS provided five mobile units in the province to assist with COVID-19 testing and sampling. These mobile units also came in handy supporting the COVID-19 testing demand at key border posts when the borders to neighbouring countries opened in December 2020, and over 2021 Easter weekend period.

Gauteng

Despite the challenges posed by the COVID-19 pandemic, Gauteng managed to achieve SANAS accreditation for three laboratories: Rahima Moosa Regional laboratory, Far East Rand Regional laboratory and Dr Yusuf Dadoo District laboratory. The region is committed to the number of accredited laboratories.

Furthermore, the province managed to establish a mobile laboratory at OR Tambo International Airport, as an extension of the Tambo Memorial laboratory, to provide international travellers with COVID-19 test results in the form of a COVID-19 certificate.

Rahima Moosa Regional laboratory

Far East Rand laboratory

Dr Yusuf Dadoo laboratory

KwaZulu-Natal

Despite the COVID-19 regulations, which limited contact and promoted virtual communication, SANAS accreditation was halted while developing new means of virtually performing laboratory assessments. When assessments were resumed, KwaZulu-Natal managed to achieve SANAS accreditation for four new laboratories. All laboratories retained their SANAS accreditation status. This included the expansion of SANAS scope for the Ngwelezane laboratory.

Contingency plans were put in place for each laboratory at each level of the lockdown, as well as risk assessments for laboratories and individuals to ensure the health and safety of employees during the pandemic. The business manager conducted business compliance visits to ensure adherence. Several laboratory visits were also conducted, as well as engagements with organised labour to maintain staff compliance and adherence. Despite social distancing, the provision of adequate personal protective equipment (PPE) and compliance with sanitisation, 114 employees tested positive for COVID-19 during the first and second waves of the virus, many of whom succumbed to COVID-19 infection. To date, 113 employees have returned to work in good health. A total of 201 NHLS employees based at INkosi Albert Luthuli Central Hospital received the Johnson & Johnson vaccine in February 2021. There were no major complications from the vaccination.

Rapid COVID-19 antigen tests were introduced at all laboratories and community health Centre (CHC), and test results available within 24 hours. Antigen testing was also provided at various hot spots for the ILembe-King Cetshwayo health districts to cater for communities and travellers entering the country at Richard's Bay harbour. In the three laboratories (Ngwelezane, Eshowe and General Justice Gizenga Mpanza) various platforms were verified and passed verification and introduced COVID-19 PCR testing. The on-site introduction of Rapid antigen testing and the COVID-19 PCR testing introduced at the three laboratories assisted in improving the turnaround time for COVID-19 within the business unit..

Limpopo

Pathologists were appointed in chemical pathology, haematology and microbiology, as well as one medical scientist in virology, to offer clinical consultation in the province. A business manager has also been appointed for the Capricorn Business Unit. The Academic Business Unit has finally been established as a stand-alone unit.

The Microbiology Department demonstrated steady growth in the research components. This was evidenced by the acceptance of abstracts for international conferences and participation as committee members of conference organising and scientific committees. The division is participating as the Limpopo study site for a national SAMRC point-of-care study.

A new Molecular Virology section was set up for SARS-COV-2 and respiratory virus testing in the Polokwane laboratory. A number of new, highly specialised items of laboratory equipment was acquired for this purpose. Two medical scientists were appointed to provide the necessary expertise and knowledge for this laboratory to function optimally.

The official opening of the molecular virology laboratory. Mr Jacob Lebudi, Area Manager, Limpopo Mpumalanga; Dr Vongani Muthambi, Clinical Virologist and Dr Phophi Ramathuba, MEC for Health in Limpopo.

Mpumalanga

COVID-19 testing was expanded in Mpumalanga, in partnership with other referral laboratories within the NHLS and private laboratories, to increase the province's testing capacity and management of SARS-COV-2 testing requests.

The business unit was able to increase the scope of its SANAS-accredited tests at the Ermelo laboratory. These tests could all be successfully accredited during the year under review. Tests included those for drugs such as valproic acid, acetaminophen, salicylates, phenytoin and carbamazepine. Among the nutritional tests introduced and to be accredited are those for iron, transferrin, ferritin, Vitamin B12 and folate. Furthermore, the business unit introduced tests for cancer markers such as α pheto proteins, CEA, CA199 and CA 125. This exercise has been able to improve service delivery and client confidence in the business unit.

Northern Cape

The Kimberley laboratory maintained its SANAS accreditation after a successful reassessment, while reducing the total number of non-conformances with 21%. The Upington and De Aar laboratories had no findings during their SANAS surveillance audits.

Western Cape

No additional district laboratories were accredited during the period under review. There were also no initial SANAS audits conducted in the Western Cape laboratories. SANAS accreditation was maintained by all the laboratories that were assessed. The assessments were either on site or via remote assessments. The Diagnostic Media Products (DMP) laboratory maintained its standards for the SABS 9001: 2015 certification.

Electron microscopy amalgamation between the Red Cross and Groote Schuur hospitals, performed at Groote Schuur Anatomical Pathology, had a positive impact on turnaround times, as well as the consolidation of equipment.

New laboratories and laboratory upgrades

Several regions undertook extensive renovations in the period under review to improve their workspace and accommodate new instrumentation to expand their laboratories' services and to upscale them for COVID-19 testing.

Eastern Cape

A new virology laboratory, sponsored by Volkswagen South Africa, was built at the Port Elizabeth Laboratory and equipped with more COVID-19 testing equipment. The laboratory was officially opened on 4 August 2020 by Premier Oscar Mabuyane and former MEC Sindiswa Gomba. It was built to support the province and improve its capacity for COVID-19 testing.

Renovations of laboratories were delayed due to COVID-19 lockdown levels 5 and 3. Only the Cradock laboratory could be renovated in the last quarter of the financial year.

Free State

The Dihlabeng Regional Hospital is busy with upgrades. The Bethlehem laboratory forms part of these upgrades. The Kroonstad laboratory managed to install new air-conditioning units during the period under review. There were major problems with regard to temperature regulation as a result of unreliable air-conditioning units that the hospital had previously installed. The Welkom laboratory is also busy with renovations to be completed in the next financial year. Phase 3 of the renovation to improve the working environment at Pelonomi was completed during the year under review.

North West

The province planned and budgeted for the revival of three more laboratories: Thusong, Wolmaransstad and Ganyesa. However, this was delayed due to COVID-19 related challenges.

Renovations were completed at Tshepong Microbiology, Mafikeng, Lehurutshe, Gelukspan, Thusong and Taung. The exercise did not only bring about beautiful laboratories, but also created safe workplaces in compliance with occupational health and safety regulations. The expansion Tshepong laboratory and its testing menu will upgrade the site to a tertiary level as the major referral site in North West.

Gauteng

Gauteng has undertaken a number of renovations to give laboratories a facelift and improve workflow. These laboratories are Kopanong, Edenvale, Kalafong and Tambo Memorial. The Tambo Memorial laboratory was renovated to accommodate COVID-19 testing analysers.

The Kopanong laboratory

The Edenvale laboratory

KwaZulu-Natal

The Floor Repair Project at the INkosi Albert Luthuli Central Hospital was completed in 2020, except for structural changes to the TB laboratory, which were supposed to continue after the lockdown. These are still pending. The restructuring of the virology laboratories was necessitated by an increase in COVID-19 testing and a COVID-19 laboratory had to be designed and established. Infrastructural challenges still exist at the laboratories at King Edward VIII Hospital. Floor repairs have been budgeted for and are still pending procurement. The damage to the windows and roof after a massive storm is pending workshop budgeting and prioritisation by the hospital management. The matter of the non-functional lift was escalated to the Department of Health in 2011, and will apparently be installed within the next six months.

Renovations took place at Ngwelezane and General Justice Gizenga Mpanza Hospital in preparation for COVID-19 PCR testing. Ngwelezane also renovated a section for the testing of HIV PCR. Other projects could not continue due to the shift in focus due to COVID-19.

Limpopo

Minor renovations were successfully completed at the Philadelphia and WF Knobel laboratories. This improved laboratory space, working conditions and compliance to safety standards. The Bela-Bela laboratory commenced with renovations that will improve staff safety. The Zebediela laboratory moved into a new park home (mobile laboratory) to improve on laboratory space, working conditions, compliance to health and safety standards, staff morale and service delivery.

Mpumalanga

Planned building projects were revised during the period under review. These had to be rolled over to the 2022 financial year, and included Mapulaneng, Tintswalo, Shongwe, Evander and Ermelo. Minor projects were completed at Rob Ferreira. These included mould repairs, repairs to plumbing and leaking pipes, ceiling repairs, light replacements and repairs, the installation of aluminium doors and the painting of the entire laboratory. These improvements allowed the laboratory to comply with occupational health and safety requirements. The Witbank laboratory project to repair and replace the leaking roof was also completed during the financial year.

Northern Cape

The Kimberley laboratory complex opened a molecular laboratory during 2020, focusing on COVID-19 testing. The Kimberley Microbiology laboratory has been earmarked for renovations and the tender process has started. District and regional laboratories were equipped with water tanks to reduce the impact of interrupted water supply experienced in the province.

Western Cape

The COVID-19 pandemic emerged in South Africa in March 2020, resulting in an immediate need to increase testing capacity in the Western Cape, as the two pre-existing Virology departments (at Groote Schuur and Tygerberg hospitals) lacked the testing capacity due to space limitations, staff capacity and shortage of automation and instrumentation.

An empty building at Green Point Complex (GPC) was converted into a fully functional COVID-19 PCR laboratory, which became operational on 16 April 2020 and as a fully equipped and highly productive laboratory within a short period thereafter. It took the Western Cape management and staff 14 days (from 2 to 16 April) to clear the old building and implement the laboratory to issue the first test results on 16 April 2020. The laboratory conducted 300 000 tests in the period under review.

Area Manager, Nasima Mohamed pointing with a finger, directing the operations with a dedicated team at Thembalethu Clinic.

During the first wave of the virus, Groote Schuur, Tygerberg and GPC had a need for extra infrastructure to separate the COVID-19 work from routine work so as to ensure the best turnaround times for healthcare worker COVID-19 testing. An extra sample sorting, workflow and registration area was implemented to address the need for the rapid processing of COVID-19 samples.

The TB GPC staff tearoom was also refurbished.

Stakeholder relations

In general, the regions maintained strong relationships with clients such as the Department of Health, Department of Correctional Services (DCS), South African National Defence Force (SANDF) and municipalities, as well as partners of the Department of Health. To this end, regional staff attend all relevant meetings and workshops. The regions also participate in health-related campaigns and roadshows hosted by clients.

Eastern Cape

Interaction between the NHLS and the Department of Health was strengthened at both district and provincial level in the fight against the COVID-19 pandemic. NHLS pathologists conducted training for healthcare workers on the COVID-19 sample collection procedure. The Eastern Cape Department of Health organised several community screening and testing campaigns for COVID-19 in collaboration with the NHLS. These campaigns were a success with the NHLS deploying mobile laboratories to increase the number of people tested.

Staff from 29 hospitals without NHLS services on-site were trained to perform COVID-19 rapid tests and to use the community screening app to capture test results. All hospitals are testing for COVID-19 using the rapid antigen tests.

A customer satisfaction survey was conducted to measure the quality of service delivery and to identify gaps. An overall satisfaction score of 89.3% was achieved, an increase of 1.3% from the previous year.

Free State

Stakeholder engagements were disrupted by the COVID-19 pandemic, as there were restrictions in terms of movement and social distancing. Where possible, engagements were done virtually.

The managers are part of the Blood Users Committee (BLUC) for hospitals. BLUC meetings are held monthly for the Dihlabeng Regional Hospital and quarterly for district hospitals where issues like turnaround time, electronic gatekeeping, minimum clinical data sets, age analysis, consumables and other issues are discussed. Relations with the University of the Free State remained excellent and amicably cooperative, as evidenced at informal and formal meetings with the Dean at Institutional Academic Pathology Committee meetings.

North West

Due to COVID-19 disturbances, the laboratory managers continued to attend clinical meetings at their local facilities, and to conduct virtual training meetings in efforts to mitigate sample rejections. There has also been interaction between North West's laboratories and private partners such as Strategic Evaluation, Advisory and Development and the Aurum Institute for the benefit of supporting National Priority Programmes.

The Brits laboratory extended service to another non-governmental organisation (NGO), Shout It Out, which supports the screening of young females who are on ART.

Gauteng

Gauteng has a good relationship with its stakeholders. The interactions are through scheduled meetings as they use different committees that have been in existence for some time. These are committees like medical advisory committees, the Provincial Laboratory and Blood Service Committee and the District Forum.

KwaZulu-Natal

Client relation meetings and training sessions were held with the provincial and community healthcare clinics in the King Edward VIII Hospital catchment area. Web view access was enabled at the clinics and hospitals for new doctors and clinic sisters to view results. Training was conducted on rapid COVID-19 testing.

The Department of Health and NHLS management meetings were held virtually at IALCH and King Edward VIII hospitals during the financial year to discuss cost efficiencies, rejection rate monitoring, clinical and electronic gatekeeping, specimen-taking practices, laboratory and health information system challenges and the Global Green Healthy Hospital Initiative. Most meetings were Joint Operations Committee meetings to discuss COVID-19 challenges. Additional meetings were convened with the NHLS to discuss the Chemical Pathology fire, the contingency plan, the referral of specimens, the deployment of staff and clinical haematology training. Daily COVID-19 updates were provided at Joint Operations Committee meetings at the INkosi Albert Luthuli Central and King Edward VIII hospitals.

An intern orientation workshop was held at King Edward VIII Hospital in January 2021 to orientate incoming medical interns on good specimen-taking practices, minimum clinical data sets, electronic gatekeeping, TrakCare laboratory and protocols. The medical interns were also given web access to enable the viewing of laboratory results via the internet. The NHLS laboratories were invited to participate in the induction workshops for new employees at King Edward VIII Hospital on a quarterly basis, but due to the nationwide lockdown, this has been limited.

King Edward VIII Hospital's clinics were visited and issues were regularly addressed, both in person and telephonically. The SMS printers were found to be functional and operational in all the clinics. The frequency of courier collection was maintained. Increased trips to INkosi Albert Luthuli Central Hospital Virology were authorised to ensure that COVID-19 testing for King Edward VIII Hospital patients in the triage area could be performed timeously. Two additional drivers were appointed to courier samples, two of whom were part of the Chemical Pathology contingency plan and were appointed temporarily to courier chemical pathology samples to other laboratories in KwaZulu-Natal.

At INkosi Albert Luthuli Central Hospital, extended management meetings, Hlanganani meetings, penalty meetings, head of department meetings and Laboratory User Committee meetings were limited due to COVID-19, and ad-hoc meetings were attended on invitation. The clinical heads of department have been provided with test statistics to assist them with electronic and clinical gatekeeping, rejections, contamination, turnaround times, pre-ordering, future orders and enforcing compliance with the minimum clinical data set and management of COVID-19 patients. The bi-monthly Laboratory User Committee meetings were temporarily suspended due to the lockdown. The aim of these meetings was to foster good client relations, attend to operational efficiency matters, optimise clinical gatekeeping and rejections, and minimise costs.

Meetings between the NHLS and Impilo Consortium focused on the day-to-day operational issues, which involved ensuring compliance with regulations of the Department of Labour and the metro, and compliance with the public-private partnership (PPP). This includes fire damage, insurance assessments, forensic investigations, asset audits, the equipment placement cycle, power outages, floor repairs, transitional changes, infrastructural changes, security, waste disposal, and health and safety. To this end, the NHLS also had meetings with relevant subcontractors with respect to various operational and infrastructural changes and the damage caused by the fire.

The University of KwaZulu-Natal's School of Laboratory Medicine and Medical Sciences Board meetings were attended by jointly appointed staff members. School meetings were held with the NHLS' academic staff. These were chaired by Dr Suvira Ramlall, who is the coordinator of the Registrar Programme. Discussions revolved around motivating academics to pursue postgraduate studies, in particular PhD degrees, key performance areas, the undergraduate curriculum, postgraduate support, the visual learning project and the ROBOT system. Many meetings had to be held virtually due to the COVID-19 regulations.

Meetings of the Institutional Academic Pathology Committee (IAPC) were held to address operational and academic matters escalated from PMC level and other matters, as per the umbrella agreement. The local bilateral agreement between the University of KwaZulu-Natal and the NHLS' KwaZulu-Natal Academic Complex has not yet been signed off by the University. The School's operational manager also attended the PMC meeting to ensure that academic challenges are highlighted and resolved, and that teaching, training and research platforms are optimised for delivery.

Constant interaction with clients has strengthened relationships with the NHLS' partners, the Departments of Health, Agriculture, Forestry and Fisheries, SANDF, DCS and municipalities. This interaction takes place at all levels: laboratory managers attending hospital management meetings, primary healthcare meetings and clinic visits, business managers attending district health meetings, city health meetings and visits, etc.

The appointment and involvement of an on-site pathologist (microbiologist) at Ngwelezane laboratory has improved confidence with the Department of Health. The NHLS has been commended for this decision. An outreach service coverage for other departments is still provided to all levels by means of various communication channels made available to the NHLS and the Department of Health.

Constant interaction with clients has strengthened the relationship with the provincial Department of Health. This interaction happens at primary healthcare, hospital and district levels. Clients' training needs are a priority and training is provided on request or as and when the need arises. Should the laboratory identify any challenge that will compromise the quality of results or patient care, it will initiate training on a specific subject.

In November 2020, East-Boom embarked on a community outreach pap smear campaign, in which 1 236 women were successfully screened. Greys laboratory provided diagnostic support. Management attended regular COVID-19 Joint Operations Committee meetings with clinicians at departmental level to coordinate efforts to deal with the COVID-19 pandemic. The annual Business Unit Customer Satisfaction Survey was performed. In Mgungundlovu-Thukela, a 91% satisfaction rate was obtained. There was a 2% decrease from 93% in 2019 to 91% in 2020, which is negligible. The greatest improvements were noted from Appelsbosch. There was a decrease in satisfaction at Emmaus. This is largely due to the staff shortage, which impacted on service delivery.

Limpopo

Relations with stakeholders were maintained through different types and levels of engagements throughout the year. Clinic Laboratory Interface meetings were held between the Department of Health and Anova Health to review clinical laboratory services in the Capricorn and Mopani districts. Healthcare workers were trained on COVID-19 specimen collection in various districts. There were engagements with border management for improved service delivery of COVID-19 antigen testing.

Mpumalanga

Stakeholder relations in the province are continuously managed through engagements at different levels and through different programmes. Due to the restrictions imposed by the COVID-19 pandemic, most of these engagements were held virtually.

Service-level agreement review meetings were held to address the following:

- services delivered during the period under review;
- perceived quality, efficiency, effectiveness and economy of laboratory service delivery;
- timeliness of payments made by the Department of Health to the NHLS;
- other management and administrative matters as determined necessary;
- customer satisfaction on services rendered by the business unit;
- effective utilisation of SMS printers by clinicians at primary healthcare level;
- effective implementation and use of eLABS devices and the monitoring dashboard;
- liquid-based cytology uptake by the Ehlanzeni sub-districts in relation to the improved adequacy rate through migration from the conventional smear method; and
- Dr Matlhako, the resident haematopathologist, provided training to clinicians in the province on performing bone marrow aspirate and trephine biopsies.

In addition, engagements were held with the following stakeholders:

- Mpumalanga Department of Health
  - Prevention of mother-to-child transmission (PMTCT) meetings were held with the Mpumalanga Department of Health where the performance on the HIV Mother-to-child Transmission Programme was presented. Challenges experienced by laboratories with regard to high rejection rates due to electronic gatekeeping were presented to the Department, and ways to curb or reduce these were shared with stakeholders.
  - Laboratory and Blood Transfusion Committee meetings were attended where inputs were made to improve on the management of costs and sample rejections in pathology services by the various district hospitals.
  - There were also engagements with Port Health Management to discuss operational plans, address operational issues and identify gaps that hamper services at the three borders within the business unit.
  - World TB Day was commemorated on 24 March and was hosted by the Ehlanzeni District Municipality in partnership with all stakeholders, including the NHLS.

NHLS in support of World TB Day.

- **Non-governmental organisations**
  - Collaboration took place between the Mpumalanga Department of Health, the NHLS and the eLABS team on the implementation of the eLABS project in Mpumalanga. This partnership was established to ensure that all stakeholders worked together to address operational challenges identified using the devices and monitoring the eLABS dashboard on a regular basis.
  - Right-to-care meetings took place on service delivery issues in partnership with the Mpumalanga Department of Health.

Northern Cape

The client liaison officer actively engages clients at all levels. Her duties include the training of clients on relevant laboratory processes, procedures and technology at facility level. Lockdown regulations impacted on the training programme and training was mostly conducted remotely. A total of 253 healthcare workers were trained.

Western Cape

Continuous engagement took place with the provincial Department of Health, City of Cape Town Health, SANDF and DCS. This was made possible due to electronic meeting applications, which allowed up-to-date information sharing and planning for testing capacity and the mitigation of logistical challenges. The assistance of the SANDF during the first and second waves of the virus to facilitate patient testing at non-health facilities was greatly appreciated.

Conclusion

Despite all the challenges and some targets not being met due to the COVID-19 pandemic, as well as delays experienced due to the nationwide lockdown, the NHLS laboratory service managed to offer a sustainable service delivery with the resources and expertise at its disposal. Stakeholder relations were strengthened in all spheres.

The executive management offered tremendous support to ensure resource availability to enable a seamless response to the demand of COVID-19 testing. Laboratory capacity was increased immensely through SANAS accreditation, the procurement of new machinery and the duplication of service delivery. The NHLS employees remained committed to excellent service delivery despite the challenges and continued to work hard in these tough times.

The NHLS continues to strive for excellent service delivery while fully meeting its goals.

2.4.2 National Priority Programmes

Prof Wendy Stevens
Director

Dr Pedro da Silva
Operations Manager

Overview

During 2020/2021, the National Priority Programmes (NPP) devoted significant resources to assist with COVID-19 preparedness, response and diagnostic activities:

- conducting landscape reviews of molecular, serology and antigen-based diagnostic modalities (1 086 assays);
- compiling validation protocols for molecular, serology and antigen assays;
- establishing standardised serology panels for evaluating antibody/antigen-based rapid test kits;
- reviewing and testing collection material and new collection approaches;
- sourcing reference material for validations and quality assurance aspects;
- completing 115 platform evaluations;
- preparing evaluation reports and engagement with regulatory bodies, such as the South African Health Products Regulatory Authorities (SAHPRA) with 48 diagnostic tests recommended for use;
- completing capacity assessments for the integration of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) testing and leveraging existing diagnostic platforms, such as the Roche Cobas, Abbott m2000 and GeneXpert;
- engaging in the rapid scale-up of SARS-CoV-2 diagnostic testing using existing high-throughput diagnostic platforms
- assisting with grant funding for additional reagents and consumables;
- performing data analytics to monitor assay performance and guide continuous quality monitoring and presentation to stakeholders such as the Virology Expert and COVID-19 variant committees;
- engaging in active participation in advisory boards (Prof Wendy Stevens, appointed member of the COVID-19 Ministerial Advisory Committee); and
- rolling out African Society for Laboratory Medicine (ASLM)-certified rapid antigen testing to master trainers, trainer-of-the-trainers and end-users.

Furthermore, the NPP continued to offer multidisciplinary services to the national diagnostic testing programmes that serve to support South Africa's human immunodeficiency virus (HIV) and tuberculosis (TB) programmes.

The following activities are noteworthy:

- the impact of the COVID-19 pandemic on testing numbers was most significant for the detection of TB-diseased individuals, with ~30% less tested than in 2019/20;
- Xpert MTB/RIF Ultra testing across 165 laboratories was successfully transitioned to version 2 of the cartridge following the completion of a cross-sectional multisite evaluation, which demonstrated 97.2% concordance across all specimen types (pulmonary and extra-pulmonary); and

- despite all the constraints imposed by the pandemic, implementation of the HIV viral load tender was successfully completed early in 2021 with six high-throughput laboratories offering Roche's Cobas 8800 testing and 10 medium-throughput laboratories offering Abbott's Alinity m testing.

Programmatic monitoring and performance, ongoing research and grant-funded activities conducted in 2020/21 are detailed below.

NATIONAL DIAGNOSTIC TESTING SERVICES: TUBERCULOSIS PROGRAMME

National Xpert MTB/RIF Ultra Testing Programme

Overview

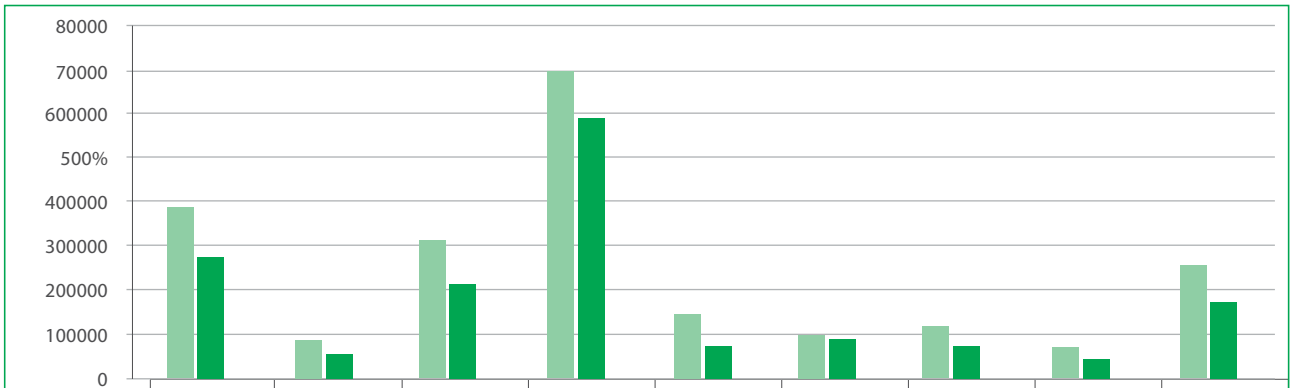
The NPP has been responsible for the implementation and programmatic monitoring of GeneXpert MTB/RIF testing and platforms for more than a decade. In 2017, the programme transitioned to Xpert MTB/RIF Ultra, which is performed across 165 testing laboratories using 325 GeneXpert platforms of varying capacity (127: GX4, 189: GX16, 1: GX48 and 8: GX80).

Operations

Since the inception of the programme, 18.7 million tests have been performed, which includes 6.4 million Xpert MTB/RIF Ultra tests. Of these, 1.85 million cases of TB were identified (9.9%), of which 6% reported rifampicin resistance.

Between April 2020 and March 2021, 1 572 831 Xpert MTB/RIF Ultra tests were conducted nationally. The highest number of tests were performed by the following four provinces:

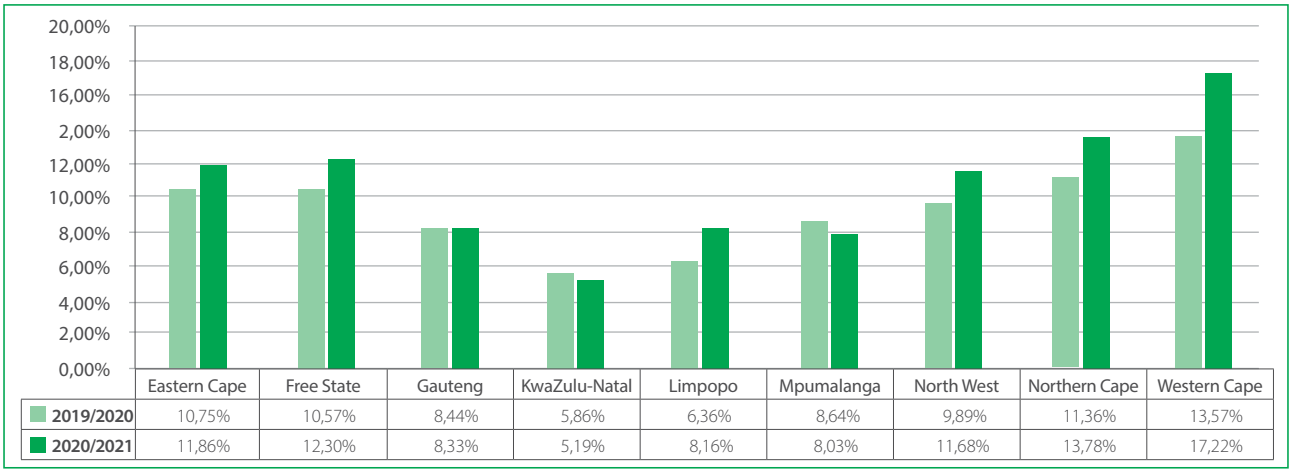
- KwaZulu-Natal: 37.3%
- Eastern Cape: 17.8%
- Gauteng: 13.8%
- Western Cape: 10.8%



	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape
2019/2020	391285	88817	315575	704282	145927	100913	116756	68111	262478
2020/2021	279459	51703	217832	586197	75700	77676	70364	41664	169955

Figure NPP1: Xpert MTB/RIF Ultra provincial tested volumes for 2019/20 and 2020/21

The average national TB positivity rate, among those tested, was 9.1% (8.8% in 2019/20). The Western Cape reported the highest positivity rate (17.2%) and KwaZulu-Natal the lowest (5.2%) The trend remains unchanged from 2019/20. The average rifampicin-resistance detection rate for the period was 5.1% (5.2% in 2019/20). KwaZulu-Natal reported the highest rifampicin-resistance rate of 6.7%, followed by Mpumalanga at 6.5%, while North West reported the lowest rate at 4.0%.



	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape
2019/2020	10,75%	10,57%	8,44%	5,86%	6,36%	8,64%	9,89%	11,36%	13,57%
2020/2021	11,86%	12,30%	8,33%	5,19%	8,16%	8,03%	11,68%	13,78%	17,22%

Figure NPP2: Xpert MTB/RIF Ultra provincial positivity rates for 2019/20 and 2020/21

Tested volumes declined significantly from the previous financial year, largely due to the COVID-19 pandemic. The following COVID-19 containment measures may have contributed directly to declining Xpert MTB/RIF Ultra test requests:

- general limitation on movement and services, e.g. the unavailability of public transport during the various lockdown levels;
- patients being hesitant to seek medical services amid fears of contracting COVID-19; and
- requirement to expectorate sputum for TB testing was viewed as an aerosolising procedure with concerns over transmission risk for COVID-19.

Figure NPP3 highlights the impact of COVID-19 on the number of specimens collected and tested for the diagnosis of active TB disease. A significant decline in Xpert MTB/RIF Ultra testing is noted from the onset of COVID-19 Lockdown Level 5. Testing volumes recovered as levels of restriction were lifted.

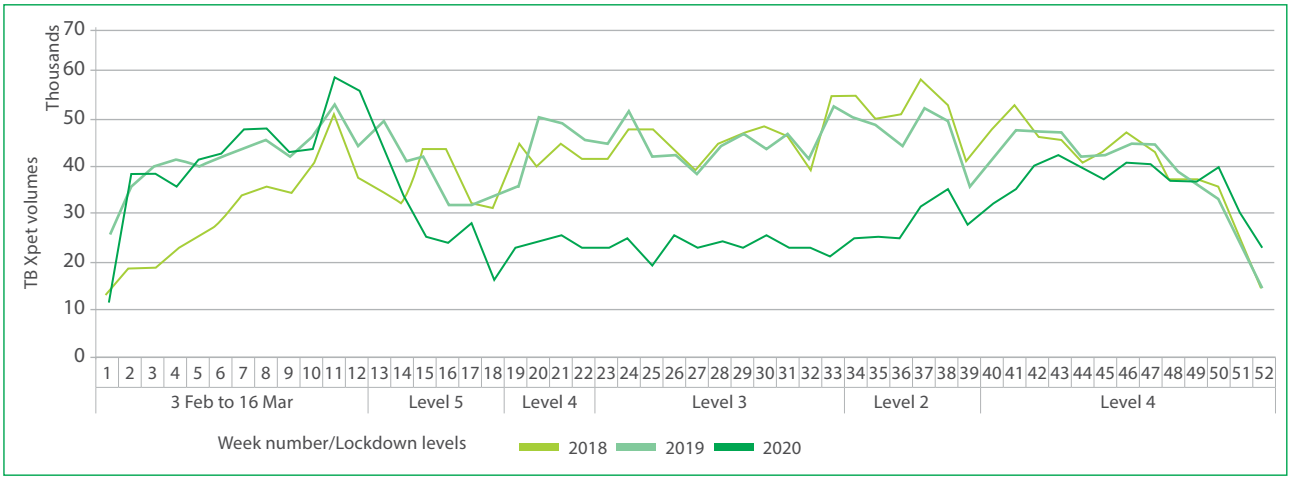


Figure NPP3: Impact on Xpert MTB/RIF Ultra testing in 2020 by various levels of lockdown implemented to contain the spread of SARS-CoV-2, compared to previous years

The improved sensitivity of Xpert MTB/RIF Ultra is largely due to detection of "trace" amounts of *Mycobacterium tuberculosis,* representing the lowest measurable level of genetic material due to the amplification of specific insertion sequences. Of all results reported in the period under review, 1.6% detected "trace" (1.9% reported in 2019/20). Provincial differences were noted with the Western Cape reporting the highest "trace" detection rate (2.2%) and KwaZulu-Natal recording the lowest (0.9%).

During 2020/21, 94.6% of Xpert MTB/RIF Ultra tests were performed within the 40-hour target, exceeding the NHLS' Annual Performance Plan (APP) target of 91%.

Continuous monitoring of the programme was provided through analysis of test volumes, instrument utilisation, turnaround time, detection rates, resistance rates and error rates. Monitoring reports were compiled and distributed to area and business managers monthly.

To ensure testing quality, all Xpert laboratories are enrolled in the SmartSpot Quality (Pty) Ltd external quality assessment (EQA) programme using dried culture spots (DCS). Three cycles of EQA were distributed in 2020/21 with 98% of Xpert laboratories submitting results for assessment. The outcome of the assessments are communicated with the National QA Division and individual laboratories. Interventions are triggered where performance has not been adequate. It is not common practice to highlight performance of laboratories on public domains.

Output

Training

The team continued to provide technical training to laboratory staff. Due to restrictions associated with COVID-19, no advanced training workshops (usually held in collaboration with Cepheid) were held. However, basic technical training activities were offered via virtual platforms and provided via www.TBGxMonitor.com. The online training programme comprises six podcast sessions with knowledge assessed upon completion of each module. In 2020/21, 108 laboratory staff completed the training.

Good Laboratory Practice training for Xpert testing laboratories was set up and offered online to 83 attendees, addressing specific needs associated with Xpert testing. In addition, on-site, troubleshooting support visits were completed for 30 laboratories.

National validation and transition to Xpert MTB/RIF Ultra version 2.0

The Xpert MTB/RIF Ultra test is designed to increase the detection of TB cases, particularly among patients living with HIV, and still detect resistance to rifampicin using the same volume of specimen. South Africa, as one of the first countries to transition to Xpert MTB/RIF Ultra, did so using version 1.0 of the cartridge in 2017. Subsequently, an improved version of the Xpert MTB/RIF Ultra cartridge version 2.0 was made available by the manufacturer, with the following changes:

- enzyme increases to extend product stability to 12 months;
- new reflector tubes to improve manufacturability; and
- realignment of semi-quantitative results with Xpert MTB/RIF (G4 version) for uniformity across both assays with cycle threshold values remaining unaffected.

As other countries transitioned to Xpert MTB/RIF Ultra, they did so using version 2.0. South Africa was thus the only country utilising version 1.0, and a dedicated production line was established for South Africa. To mitigate supply chain risks, South Africa's transition to version 2.0 was considered.

A cross-sectional multisite evaluation study was set up to verify the use of the version 2.0 cartridge on pulmonary and extrapulmonary specimens at four NHLS laboratories:

- Mycobateriology Referral Laboratory, Braamfontein.
- Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).
- Port Elizabeth.
- Green Point Laboratory.

Similar diagnostic performance was demonstrated between both version 1.0 and version 2.0 cartridges and across all specimen types with 97.2% concordance achieved. For rifampicin-resistance profiling, where results were available for both assays, absolute concordance was seen in all specimens.

Based on the findings, the Xpert MTB/RIF Ultra programme successfully transitioned from version 1.0 to version 2.0. This was implemented in a phased approach. The national transition was completed successfully in 2020/21.

Publications

Experience gained with the Xpert MTB/RIF Ultra EQA was presented virtually at the 51st World Conference on Lung Health of the International Union against Tuberculosis and Lung Disease from 20 to 24 October 2020[1]. Furthermore, as one of the first countries to transition to Xpert MTB/FIR Ultra, South Africa presented its experiences in dealing with the clinical management of "trace" results at a multi-country workshop at the same conference[2, 3].

NATIONAL DIAGNOSTIC TESTING SERVICES: COVID-19

Xpert Xpress SARS-CoV-2 Testing Programme

Overview

In March 2020, Cepheid's Xpert Xpress SARS-CoV-2 assay received emergency Food and Drug Administration (FDA) approval to support the COVID-19 scale-up testing as a rapid reverse-transcriptase polymerase chain reaction (RT-PCR) test intended for the qualitative detection of SARS-CoV-2 RNA from either a nasopharyngeal, oropharyngeal swab or nasal wash/aspirate specimens. The NHLS leveraged on its existing GeneXpert footprint (primarily used for TB testing) and maximised its spare capacity to support COVID-19 testing in record time. The available spare GeneXpert monthly capacity was determined at a minimum of 400 000 tests, translating to ~45% spare capacity (~15 000 tests in 24 hours), subject to reagent availability.

The Xpert platform allows for random access across the testing modules with the Xpert Xpress SARS-CoV-2 test requiring ~45 minutes for a result. This is considerably shorter than the Xpert MTB/RIF Ultra, for TB testing, which requires ~135 minutes for a result. A fast-tracked rollout of the Xpert Xpress SARS-CoV-2 assay was implemented from April 2020, with online training arranged for key laboratory staff to ensure an understanding of assay principles and result management. The training programme was designed for technologists and technicians who were already technically involved in performing other Xpert assays.

Operations and output

Once Xpert Xpress SARS-CoV-2 had received emergency approval by the FDA, the NPP completed a national validation prior to implementation. Rollout of the assay was initiated on 17 April 2021 at selected sites across all nine provinces (see Figure NPP4) and comprised the following activities:

- site-readiness checklists were prepared and shared with individual laboratory managers to complete;
- standard operating procedure (SOP) GPL4406: Procedure for processing specimens using the Xpert Xpress SARS-COV-2 assay was drafted, approved and loaded onto Q-Pulse for testing sites to access;
- interface testing was completed to allow for results transmission to TrakCare;
- software updates were shared with proposed testing sites to allow for test code activation;
- verification panels (supplied by SmartSpot Quality (Pty) Ltd) were shipped to proposed testing sites (see Figure NPP5), and once the sites had completed verification, results were submitted online; and
- technical training sessions were held with 324 staff members attending online training and completing written assessments.

Rollout was subsequently extended to include mobile Xpert laboratories that conduct testing at ports of entry.

For the rollout of the Xpert Xpress SARS-COV-2 assay, each GeneXpert system was verified using both a positive and a negative COVID-19 specimen to demonstrate that the system was fit-for-purpose. As a component of quality assurance, all laboratories are required to have a verification report for each of the Xpert modules.

[1] Marokane P, Radebe M, Da Silva P, Scott L, Stevens W. South Africa's Xpert MTB/RIF Ultra EQA experience – need for good laboratory practice to minimize contamination. 51st World Conference on Lung Health of the International Union Against Tuberculosis and Lung Disease, virtual event. 20-24 October 2020.

[2] Da Silva P. Xpert® MTB/RIF Ultra sensitivity – implementation and clinical management workshop. South African experience: Algorithms and programmatic considerations. Workshop presentation and discussion, 51st World Conference on Lung Health of the International Union Against Tuberculosis and Lung Disease, virtual event. 20-24 October 2020.

[3] Da Silva P. Xpert® MTB/RIF Ultra "trace" management case study. Implementation and clinical management workshop. South African experience: Algorithms and programmatic considerations. Workshop case study presentation, 51st World Conference on Lung Health of the International Union Against Tuberculosis and Lung Disease, virtual event. 20-24 October 2020.

Figure NPP4: GeneXpert operator, Thandokazi Nkomana, conducting Xpert Xpress SARS-CoV-2 testing at the Mafikeng laboratory

Figure NPP5: Xpert Xpress SARS-CoV-2 verification panel manufactured by SmartSpot Quality (Pty) Ltd for Xpert module verification

To monitor quality of testing, all Xpert Xpress SARS-CoV-2 testing laboratories were enrolled in the SmartSpot Quality (Pty) Ltd DCS SARS-CoV-2 EQA programme. Two EQA cycles (87 panels) were distributed in the period under review, each consisting of 4-DCS to be tested. Consolidated reports on laboratory performance were distributed to NHLS Quality Assurance and area managers at the end of each EQA cycle.

For the period under review, 583 912 Xpert SARS-CoV-2 tests were conducted under the GeneXpert programme. Testing volumes varied by month with an average of ~48 000, peaking in December 2020 (69 715) and January 2021 (80 425), coinciding with South Africa's second wave of COVID-19 infections.

NATIONAL DIAGNOSTIC TESTING SERVICES: HIV PROGRAMME

National CD4 Count and Reflex Cryptococcal Antigen Testing Programme

Overview

CD4-count testing, although not essential for initiating HIV therapy since the introduction of universal test and treat guidelines[4,5,6], is still valuable for the management of HIV-infected patients in South Africa[7,8]. Testing at 47 laboratories across nine provinces provided a standardised national service for the assessment of patient immune status and the identification of underlying infections such as cryptococcal meningitis[9] in immune-compromised patients. The CD4 team provided ongoing training through regular site visits and audits and by assisting laboratories with accreditation readiness. The CD4 team was also responsible for standardisation across the network, with the distribution of SOPs, monitoring laboratory performance through weekly turnaround time reports, assisting with corrective actions where needed and monitoring performance on internal and external EQA schemes. The team continued to contribute through meetings, online lectures, conference attendances and the publication of research outcomes.

[4] World Health Organization (WHO). Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. Guideline. Geneva, Switzerland. July 2017.

[5] Lilian RR, Rees K, McIntyre JA, Struthers HE, Peters RPH. Same-day antiretroviral therapy initiation for HIV-infected adults in South Africa: Analysis of routine data. PLoS One. 2020;15(1):e0227572. https://doi.org/10.1371/journal.pone.0227572.

[6] Renju J, Rice B, Songo J, Hassan F, Chimukuche RS, McLean E, Kalua T, Kajoka D, Geubbels E, Moshabela M, Seeley J, Wringe A. Influence of evolving HIV treatment guidance on CD4 counts and viral load monitoring: A mixed-methods study in three African countries. Global Public Health. 2021;16(2):288-304. https://doi.org/10.1080/17441692.2020.1805785.

[7] Hirasen K, Fox MP, Hendrickson CJ, Sineke T, Onoya D. HIV treatment outcomes among patients initiated on antiretroviral therapy pre- and post-universal test and treat guidelines in South Africa. Therapeutics and Clinical Risk Management. 2020;16:169-180. https://doi.org/10.2147/TCRM.S227290.

[8] Fiorentino M, Nishimwe M, Protopopescu C, Iwuji C, Okesola N, Spire B, Orne-Gliemann J, McGrath N, Pilay D, Dabis F, Larmarange J, Boyer S. Early ART initiation improves HIV status disclosure and social support in people living with HIV, linked to care within a universal test and treat programme in rural South Africa (ANRS 12249 TasP Trial). AIDS Behaviour. 2021;25(4):1306-1322. https://doi.org/10.1007/s10461-020-03101-y.

[9] Govender NP, Glencross DK. National coverage of reflex cryptococcal antigen screening: A milestone achievement in the care of persons with advanced HIV disease. South African Medical Journal. 2018;108(7):534-535. https://doi.org/10.7196/SAMJ.2018.v108i7.13094.

Operations

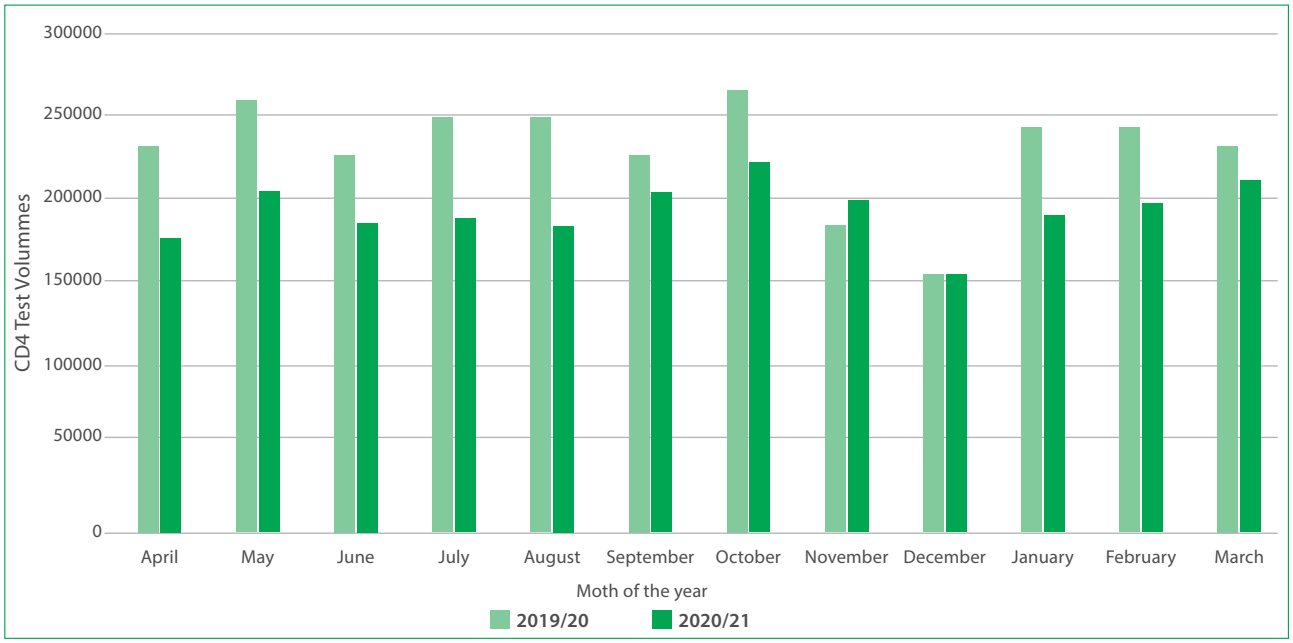
During 2020/21, the CD4 training team conducted the following activities:

- audited three sites to assist laboratories in preparing for South African National Accreditation System (SANAS) accreditation or internal audits;
- provided interventions and troubleshooting at 21 sites to assist laboratories with identified issues;
- provided on-site and/or virtual training at 17 sites to support new instrument installations or newly appointed staff members;
- assisted with the verification of additional instruments or instrument replacements at nine sites; and
- switched instrumentation to the Aquios system at Frere laboratory in October 2020.

CD4 testing

A significant decline in national testing volumes was reported between 2019/20 and 2020/21 ($p<0.1$), with 15% less tests requested. However, there was a recovery in CD4 test volumes between November and December 2020, and in March 2021 (see Figure NPP6). The programme has seen a year-on-year decline in CD4 test volumes of ~5%, but this was exacerbated by the COVID-19 pandemic in 2020/21. At provincial level, the testing volume decrease ranged from 9% in the Northern Cape to 19.7% in the Free State. The percentage contribution of test volume per province ranged from 2.4% in the Northern Cape to 35.8% in KwaZulu-Natal and 20.2% in Gauteng.

Figure NPP6: CD4 test volumes per month for 2019/20 and 2020/21

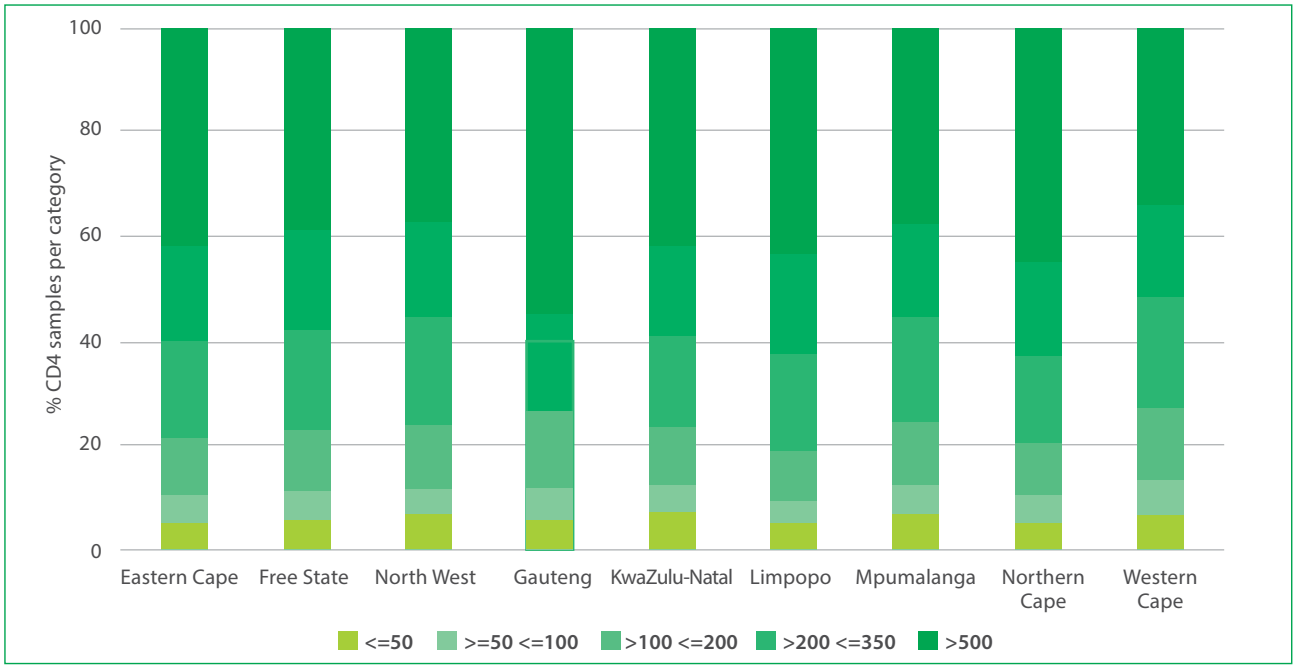


Analyses of CD4 test volumes per CD4 result category showed that 10.7% of all tested specimens had counts under 100 cells/µl. A further 10.8% reported counts between 100 and 200 cells/µl. Specimens with counts between 200 and 350, and between 350 and 500 cells/µl showed little variability between provinces, with approximately 18 ±1% contribution per group to the total tested volume. Specimens with CD4 counts over 500 cells/µl made up 43.4 ±6% of the total specimens tested.

The provincial breakdown per CD4 category (see Figure NPP7) shows that KwaZulu-Natal reported the highest percentage of specimens with CD4 counts over 500 cells/µl at 54.8%, while the Western Cape had the lowest percentage at 33.7% for this category. While the distribution of specimens with CD4 counts between 200 and 500 cells/µl were evenly distributed across provinces (18.4%), the distribution of specimens with counts between 100 and 200 cells/µl was highest in the Western Cape (13.8%) and lowest in KwaZulu-Natal (5.4%). This pattern was similar for specimens with CD4 counts under 100 cells/µl with the highest contribution (13.2%) from the Western Cape and the lowest (5.4%) from KwaZulu-Natal.

Figure NPP7: CD4 tests per CD4 category range by province in 2020/21

Province	<= 50	> 50 <= 100	<100	> 100 <= 200	> 200 <= 350	> 350 <= 500	> 500
Eastern Cape	6.00	5.06	11.06	10.90	18.32	18.51	41.21
Free State	6.08	5.26	11.33	11.51	19.35	18.84	38.97
Gauteng	6.66	5.18	11.84	12.07	20.19	18.86	37.04
KwaZulu-Natal	2.84	2.54	5.38	6.61	14.39	18.75	54.87
Limpopo	7.25	5.08	12.32	10.70	17.83	17.85	41.30
Mpumalanga	5.02	4.07	9.09	9.83	18.26	19.37	43.45
North West	6.77	5.68	12.46	12.20	19.58	18.39	37.37
Northern Cape	5.25	4.75	9.99	9.85	17.07	18.54	44.55
Western Cape	6.98	6.23	13.21	13.85	21.00	18.14	33.79



Laboratory turnaround time performance demonstrated an average turnaround time across all CD4 laboratories of 14.3 hours (ranging from 12.4 to 16.1 hours), with more than 90% of all specimens tested meeting the 40-hour cut-off.

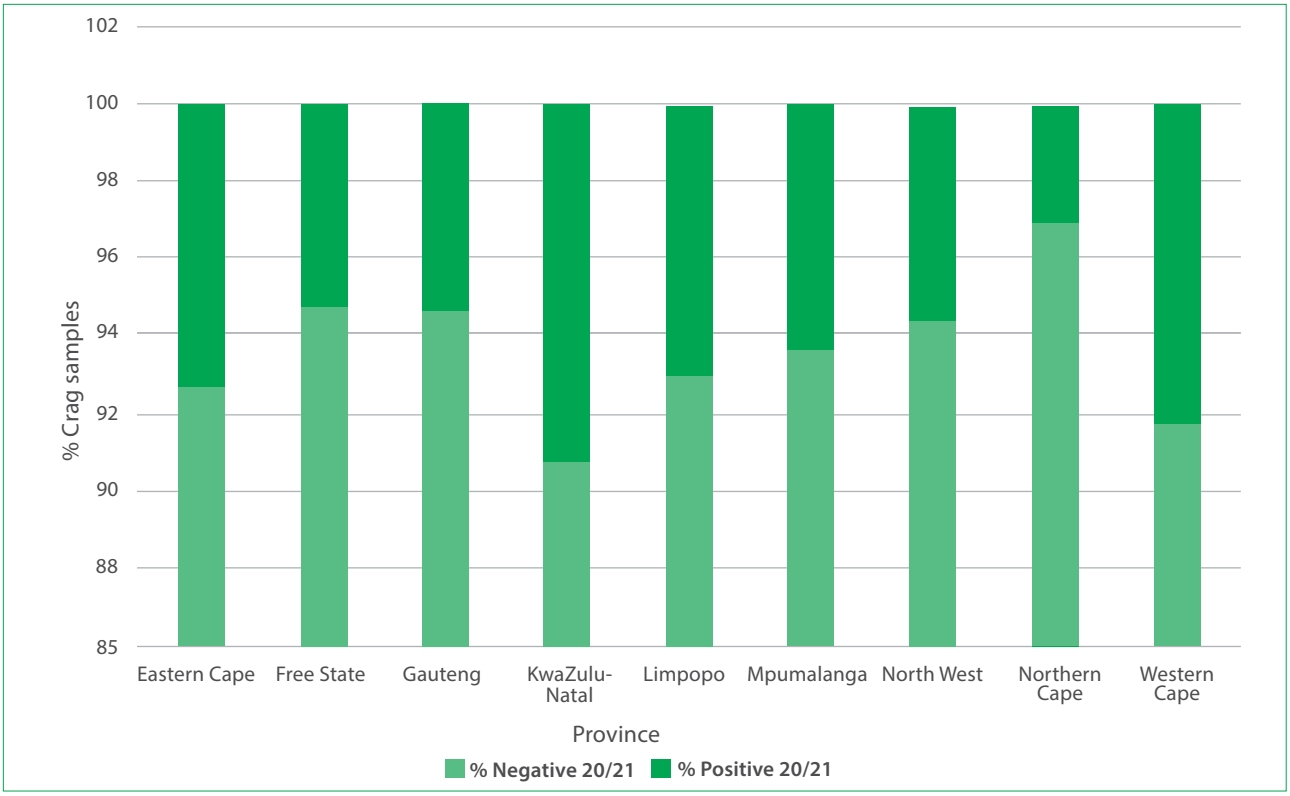
Cryptococcal antigen testing

Nationally, 10.3% of all CD4 specimens tested had CD4 counts under 100 cells/µl and qualified for the reflexed cryptococcal antigen (CrAg) test. For the period under review, 98% of reflexed CrAg testing was completed within 24 hours of CD4 testing. The total number of CrAg tests performed followed the CD4 trend, with a statistically significant decrease of 19.3% from 268 976 specimens in 2019/20 to 213 956 in 2020/21.

Gauteng contributed the highest CrAg test volumes (26.1%), followed by 19.7% and 12.5% for KwaZulu-Natal and the Eastern Cape, respectively. The CrAg positivity rate was highest in KwaZulu-Natal at 9.3% (an increase from 8.9% in 2019/20), followed by the Western Cape at 8.3%, with the lowest positivity rate recorded in the Northern Cape at 3.1% (a decline from 4.8% in 2019/20). The national CrAg positivity rate for 2020/21 was 6.4% (6.5% in 2019/20) (see Figure NPP8).

Figure NPP8: Distribution of the percentage of cryptococcal antigen positivity by province for 2020/21

	% Positive 2019/2020	%Negative 2019/2020	%Positive 2020/2021	%Negative 2020/2021
Eastern Cape	7,58	92,43	7,42	92,58
Free State	4,34	95,66	5,22	94,78
Gauteng	5,19	94,81	5,47	94,53
KwaZulu-Natal	8,97	91,03	9,31	90,69
Limpopo	6,18	93,83	6,98	93,03
Mpumalanga	5,82	94,18	6,54	93,46
North West	5,22	94,79	5,54	94,46
Northern Cape	3,07	96,93	3,05	96,95
Western Cape	7,34	92,66	8,26	91,74



Output

In anticipation of the local changes to Department of Health CrAg testing guidelines and inclusion of specimens with CD4 counts between 100 and 200 cells/µl, a large-scale prevalence/incidence study was conducted in November 2020 across all 47 CD4 laboratories. Preliminary data indicates that, although the test number per laboratory for the 100–200 cells/µl category are very similar to the number of specimens with counts less than 100 cells/µl (the current threshold for CrAg reflex testing), the positivity rates are significantly lower at 2.2% (6.4% for 100–200 cells/µl category), ranging from 0.9% in the Free State to 3.9% in KwaZulu-Natal. Additional data analyses are being completed to assess if extending the threshold for CrAg testing to less than 200 cells/µl would be cost effective and at what threshold.

The CD4 team continues with operational research on turnaround time, test validations, the impact of rural CD4 test facilities, CrAg positivity rates distribution, etc. Eleven publications were published in peer-reviewed journals[10,11,12,13,14,15,16,17,18,19,20], seven as first author. A virtual poster was accepted to the 16th World Congress on Public Health's virtual conference (12-16 October 2020), and two poster presentations were presented at the virtual workshop of the INTEREST 2020 International Conference on HIV Treatment, Pathogenesis and Prevention Research in Research-limited Settings (30 November to 4 December 2020)[22,23].

National HIV Viral Load Testing Programme

Overview

South Africa, with 7.89 million[24] people living with HIV, still accounts for the largest HIV epidemic in the world. The NHLS supports the DoH's National HIV Programme by providing HIV viral load (VL) tests at 16 centralised laboratories across eight provinces in South Africa, with more than 5 million tests conducted annually. Unlike Xpert MTB/RIF Ultra and CD4 count testing, which were affected by the COVID-19 pandemic, HIV VL testing remained largely unaffected. Despite seeing an initial reduction in the number of HIV VL tests performed during the Level 5 restrictions and diversion of some of the existing HIV VL instrumentation to assist with SARS-CoV-2 testing, the number of HIV VL tests performed for the remainder of the fiscal period returned to expected levels and met the anticipated testing targets.

Operations

During 2020/2021, 5.8 million HIV VL tests were performed, compared to 5.7 million during 2019/20, constituting a 1.85% increase. Of these, 87.1% met the WHO's definition of viral suppression [25], i.e. less than 1 000 copies/ml).

Monthly test volumes varied between 382 545 and 557 527. Regionally, KwaZulu-Natal processed the highest percentage of HIV VL tests, with 1 720 983 (29.6%), followed by Gauteng with 1 358 525 (23.4%). The Northern Cape performed the lowest number of HIV VL tests, with 72 283 (1.2%).

The HIV VL tender (RFB017/18-19), adjudicated to Roche (on the Cobas 8800 platform) for six high-throughput laboratories, and Abbott (on the Alinity m platform) (see Figure NPP9) for ten medium-throughput laboratories, was successfully implemented and completed at all 16 HIV VL laboratories by January 2021. Despite the numerous challenges imposed by COVID-19, such as travel restrictions, lockdown measures affecting critical laboratory renovations, staffing constraints due to increased COVID-19 sampling and testing volumes, inbound stock challenges due to global demand for shared reagents, and challenges associated with a new technology (Abbott's Alinity m), perseverance and determination culminated in a successful roll-out.

[10] [10] Botha S, Maphayi MR, Cassim N, George JA. Vitamin D [25(OH)D] and 1,25(OH)2D serum concentrations in patients tested at the Charlotte Maxeke Johannesburg Academic Hospital. Journal of Endocrinology, Metabolism and Diabetes of South Africa. 2021:1-8.

[11] Cassim N, Ahmad A, Wadee R, George JA, Glencross DK. Using systematised nomenclature of medicine clinical term codes to assign histological findings for prostate biopsies in the Gauteng province, South Africa: Lessons learnt. African Journal of Laboratory Medicine. 2020;9(1):909.

[12] Cassim N, Ahmad A, Wadee R, Rebbeck TR, Glencross DK, George JA. Prostate cancer age-standardised incidence increase between 2006 and 2016 in Gauteng province, South Africa: A laboratory data-based analysis. South African Medical Journal. 2020;111(1):26-32.

[13] Cassim N, Coetzee LM, Glencross DK. Categorising specimen referral delays for CD4 testing: How inter-laboratory distances and travel times impact turnaround time across a national laboratory service in South Africa. African Journal of Laboratory Medicine. 2020;9(1):1120.

[14] Cassim N, Coetzee LM, Tepper MEE, Perelson L, Glencross DK. Timely delivery of laboratory efficiency information, Part II: Assessing the impact of a turnaround time dashboard at a high-volume laboratory. African Journal of Laboratory Medicine. 2020;9(2):948.

[15] Cassim N, Tepper ME, Coetzee LM, Glencross DK. Timely delivery of laboratory efficiency information, Part I: Developing an interactive turnaround time dashboard at a high-volume laboratory. African Journal of Laboratory Medicine. 2020;9(2):947.

[16] Coetzee LM, Cassim N, Glencross DK. Weekly laboratory turnaround time identifies poor performance masked by aggregated reporting. African Journal of Laboratory Medicine. 2020;9(1):1102.

[17] Glencross DK, Cassim N, Coetzee LM. Documented higher burden of advanced and very advanced HIV disease among patients, especially men, accessing healthcare in a rapidly growing economic and industrial hub in South Africa: A call to action. South African Medical Journal. 2020;110(6):505-513.

[18] Madhi SA, Gray GE, Ismail N, Izu A, Mendelson M, Cassim N, Stevens W, Venter F. COVID-19 lockdowns in low- and middle-income countries: Success against COVID-19 at the price of greater costs. South African Medical Journal. 2020;110(8):724-726.

[19] Maphayi MR, Cassim N, Bello B, George JA. Mining laboratory data to describe prostate specific antigen testing and prostate cancer in Johannesburg, South Africa. Pan African Medical Journal. 2020;35:61.

[20] Terris-Prestholt F, Boeras D, Ong JJ, Torres-Rueda S, Cassim N, Mbengue MAS, Mboup S, Mwau M, Munemo E, Nyegenye W, Odhiambo CO, Dabula P, Sandstrom P, Sarr M, Simbi R, Stevens W, Tucker JD, Vickerman P, Ciaranello A, Peeling RW. The potential for quality assurance systems to save costs and lives: The case of early infant diagnosis of HIV. Tropical Medicine and International Health. 2020;25(10):1235-1245.

[21] Cassim N, Coetzee LM, Glencross DK. Assessing late presentation for female adolescents and young women with HIV in 2019, South Africa. 16th World Congress on Public Health, virtual conference. 12-16 October 2020.

[22] Cassim N, Glencross, DK. Operational cost per test of cryptococcal antigen (CrAg) reflexed testing in South Africa in the light of proposed inclusion of samples with a CD4 count between 100-200cells/µl. INTEREST Workshop, virtual conference. 30 November-4 December 2020.

[23] Coetzee, LM, Cassim, N, Glencross, DK. Assessing the operational impact of guideline changes to cryptococcal antigen (CrAg) testing to include samples with a CD4 count of 100-200 cells/µl on a national reflex testing programme in South Africa: A desktop exercise using laboratory data. INTEREST Workshop, virtual conference, 30 November-4 December 2020.

[24] Statistics South Africa (StatsSA). Statistical Release P0302 Mid-year Population Estimates. 2020.

[25] World Health Organization (WHO). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection 2016. Recommendations for a public health approach, 2nd edition. 2016.

Figure NPP9: Fully renovated Addington laboratory with placement of Abbott's Alinity m analysers

The team continued to monitor and evaluate the national HIV VL programme. Test volumes and turnaround times were monitored weekly and monthly to identify challenges, ensure that timely corrective actions were instituted, and strengthen the national laboratory network service. These efforts were strengthened by continuous support and frequent on-site laboratory visits. Furthermore, it is mandatory for all HIV VL laboratories to participate in the Quality Control for Molecular Diagnostics (QCMD) and Centres for Disease Control and Prevention (CDC) HIV VL EQA programmes. The use of national SOPs ensured standardisation across the 16 HIV VL testing laboratories.

Output

Pre-analytical track systems

As part of an "add-on service" to the existing HIV VL tender, with the aim of improving the pre-analytical testing component, Roche pre-analytical track systems were installed and are operational at CMJAH, Mankweng, Rob Ferreira and Ngwelezane HIV VL laboratories. The Universitas Virology laboratory has also been earmarked for pre-analytical system installation in 2021, subject to completion of its renovation.

Training

The team conducted training on an ongoing basis, both for newly appointed and existing staff members who require refresher courses. Super-user workshops are another training intervention with the aim of better equipping personnel and laboratories with troubleshooting skills. Challenged by COVID-19 lockdown and social distancing measures, virtual user meetings were initiated at the end of Quarter 3. The first virtual meeting targeting Abbott HIV VL sites spanned two morning sessions from 23 to 24 November 2020.

Performance monitoring

Supplier dashboard development to monitor real-time HIV VL data for quality monitoring and improved performance are ongoing. The data includes tested volumes, failed test runs, testing control failures, error rates and error flags.

A key advantage of real-time access to the data is timeous decisions and the implementation of interventions. The Roche HIV VL dashboard is in its final stages of development with rollout expected at the end of Quarter 2. Abbott's Alinity m dashboard is still under development considering that the technology is fairly new.

In addition to supplier HIV VL monitoring dashboards, as part of the NHLS-CDC cooperative agreement grant, individualised laboratory HIV VL monitoring dashboards were developed. All 16 HIV VL testing laboratories were scoped to receive two monitoring screens for the visualisation of laboratory dashboards. The aim is for each HIV VL laboratory to monitor its own performance and trigger interventions, where required. To date, screens have been installed at 15 of the 16 HIV VL laboratories (see Figure NPP10). Laboratory dashboards have been completed and are awaiting software licensing as a requirement for each laboratory.

Figure NPP10: Monitoring screen for HIV VL dashboard visualisation installed and being tested at Madadeni laboratory

Regional laboratory systems strengthening

Laboratory Systems Strengthening Community of Practice (LabCoP), a division of ASLM, aimed to strengthen laboratory systems through information sharing, tools and resources that support clinical, policy, technical, scientific and programmatic aspects to aid the successful implementation of HIV VL testing, launched in 2017. The NPP is represented by Dr Lucia Hans (clinical virologist), Somayya Sarang (HIV VL National Programme Manager) and Naseem Cassim (PhD candidate and monitoring and evaluation expert). The fourth LabCoP annual meeting was held from 24 to 25 November 2020 (see Figure NPP11) with Dr Hans presenting the South African HIV VL cascade self-assessment.

As many countries are challenged with tracking the HIV VL cascade data, from demand creation to the utilisation of results for decision making, and with the emergence of COVID-19, its potential impact on public health services, and the availability and use of data for decision making became more urgent. Thus, in an effort to address these gaps, ASLM's LabCoP launched the Monitoring and Evaluation Sub-community of Practice in January 2021. The first session was convened on 4 February 2021 with the same NPP representatives actively involved.

Figure NPP11: Regional HIV VL laboratory systems strengthening at the fourth annual LabCoP meeting held virtually from 24 to 25 November 2020

National Early Infant Diagnosis HIV Polymerase Chain Reaction Testing Programme

Overview

Prevention of mother-to-child transmission of HIV is essential to attaining the global goal of ending the AIDS epidemic. The Joint United Nations Programme on HIV/AIDS (UNAIDS) last reported South Africa's mother-to-child transmission rate of 3.3% in 2019[26]. The provision of accurate infant diagnosis is crucial to reducing the infection rate to 0% and eliminating transmission.

[26] Joint United Nations Programme on HIV/AIDS (UNAIDS). Country factsheets South Africa 2019. 2020. Accessed on 22 April 2021.

The Early Infant Diagnosis (EID) HIV PCR testing programme, in collaboration with the DoH and other stakeholders, aims to do the following:

- train healthcare workers on appropriate and adequate specimen collection;
- deliver a high-quality HIV molecular diagnostic testing service;
- implement clinical management guidelines;
- monitor uptake of EID HIV PCR testing; and
- provide technical training and support to testing laboratories.

The 2019 DoH Guideline for the Prevention of Mother-to-Child Transmission of Communicable Infections provides guidance on the appropriate type and timing of infant HIV diagnostic testing[27]. It recommends that HIV PCR tests be performed at the following times:

- at birth for all HIV-exposed infants;
- at ten weeks;
- at six months; and
- at 18 months for those with previously negative HIV PCR results.

These recommendations create demand for testing and impact testing capacity needs.

Operations

The network for EID HIV PCR laboratories was expanded from nine to eleven facilities during 2020/21: Two laboratories (Ngwelezane and Edendale) were added to the existing laboratories at CMJAH, Chris Hani Baragwanath Academic Hospital (CHBAH), Tshwane Academic Hospital, Groote Schuur, Tygerberg, INkosi Albert Luthuli Central Hospital (IALCH), Port Elizabeth and Nelson Mandela Academic Hospital.

For 2020/21, 674 068 HIV PCR tests were conducted (compared to 621 028 in 2019/20), representing an 8.5% increase. Monthly tested volumes varied between 48 807 and 63 051: KwaZulu-Natal processed the highest number of tests with 177 355 (26.3%), followed by Gauteng with 159 912 (23.7%); the Northern Cape processed the lowest number of tests with 9 629 (1.4%). The infection rate decreased from 1.85% in 2019/20 to 1.48% in 2020/21.

Monitoring and evaluation of the national EID programme was achieved in collaboration with the NHLS' Central Data Warehouse (CDW), which generated two sets of reports:

- facility and results-for-action reports facilitating fast-tracking of all PCR HIV-positive paediatric individuals; and
- a missed diagnostic opportunity report, allowing the monitoring of specimen rejection rates, which, in turn, triggered training interventions to minimise rejection rates.

Intensified and comprehensive facility support visits and the provision of mentoring also assisted in reducing rejection rates and ensuring uptake of HIV PCR testing following the national guidelines.

Output

Training

Sister Tsakani Mhlongo conducts training for healthcare workers involved in the management of newly born babies and infants. Delegates included clinicians, nursing staff, counsellors and facility managers. Training activities addressed the following:

- reinforcement of national clinical management guidelines;
- dissemination of any updates implemented to the clinical management guidelines;
- identification of which babies/infants should be tested through on-site audits;
- correct administration and completion of NHLS request forms;

[27] South African National Department of Health. Guideline for the prevention of mother-to-child-transmission of communicable infections. 2019.

- collection of quality specimens to maximise HIV PCR diagnosis;
- appropriately collected specimens to minimise specimen rejection;
- interpretation of HIV rapid and HIV PCR results; and
- management of those exposed to HIV and relevant prophylactic antiretroviral therapy (ART) regimens.

In 2020/21, 1 421 healthcare workers were trained and 182 healthcare facilities supported. COVID-19-related containment restrictions impacted on training activities during the period under review.

National HIV Drug Resistance Testing Programme

Overview

There are five NHLS HIV drug-resistance testing laboratories located throughout South Africa: at the CMJAH, Tygerberg, IALCH, Universitas, and Dr George Mukhari Hospital laboratories.

HIV drug-resistance testing is still recommended in patients failing protease-based ART to guide the choice of the most suitable third-line regimen. In addition, resistance testing is now also recommended for adults and adolescents failing a dolutegravir (DTG)-based regimen, provided that patients have been exposed to DTG for at least two years and meet the definition of confirmed virological failure.

Currently, only Tygerberg and CMJAH offer integrase drug-resistance testing. Any requests for integrase testing are thus referred to these laboratories.

Operations

Across all laboratories, 4 507 specimens were processed for HIV drug-resistance testing in 2020/21, a 9% decrease from 2019/20. The COVID-19 pandemic may have impacted on annual testing volumes. Three laboratories, CMJAH (37%), IALCH (21%) and Tygerberg (20%) processed the bulk of the testing volumes. CMJAH serves as a back-up laboratory for IALCH and Dr George Mukhari, explaining the higher proportion of tests performed at CMJAH.

Four laboratories are SANAS-accredited for HIV drug-resistance testing, with Dr George Mukhari laboratory aiming to be accredited in the next fiscal year.

Output

Standardisation

A new commercial HIV drug-resistance kit was validated and will be implemented in the next fiscal year with the aim of standardising HIV drug-resistance testing nationally.

National NHLS HIV Drug-resistance Committee

Dr Kim Steegen, senior medical scientist, continued to co-chair the committee in 2020/21. The committee guides best practice and aims for standardisation across the diagnostic service.

General Practitioner Care Cell Project

Overview

The Foundation for Professional Development (FPD) and the Professional Provider Organisation Services (PPO Serve) embarked on a pilot project to implement a private general practitioner network contracting model (GP Care Cell Model), delivering HIV testing and management to two target groups:

- people living with HIV, not covered by private health insurance, but who make use of private health services on a self-funding basis; and
- people living with HIV who could not access HIV treatment in the public sector for various reasons.

The novel intervention allowed general practitioners to identify and initiate newly diagnosed HIV-infected patients onto ART using state-funded pharmaceuticals, commodities and laboratory services, while ensuring alignment with government standards, and preventing fraud and over-utilisation. The project was funded by the United States President's Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID). The pilot was initially implemented in the City of Tshwane metropolitan area with the aim of replicating and scaling it up in other districts, based on pilot findings.

The NPP's role in the pilot was to do the following:

- monitor service provision by the NHLS to the registered practitioners;
- load registered practitioner details onto TrakCare;
- provide consumables to registered practices;
- monitor the turnaround time of testing and follow up with laboratories where turnaround time was not met;
- facilitate practitioner access to laboratory results; and
- conduct regular practice visits to address any matters arising.

Operations

Due to a lack of funding, the pilot was terminated on 15 October 2020. Disappointment at the termination was relayed to DoH by the practitioners and concerns raised that enrolled patients may be lost to follow up. For the period under review (until pilot termination), 5 031 test requests were submitted to the NHLS. This was significantly less than for 2019/20 when 12 821 test requests were received, and was likely impacted on by the COVID-19 pandemic.

Initially, 55 practitioners were registered with the pilot, with only 12 remaining at its conclusion. The average number of test results reported within the turnaround time was 73.0%. Turnaround time was affected by the COVID-19 infection peaks in South Africa and requests for testing on Saturdays. The collection of specimens over the weekend necessitated prior arrangements to be made with the NHLS' logistics department.

National and provincial HIV counselling/testing and TB campaigns and events

Overview

Previously, the NHLS has supported World AIDS Day and World TB Day commemorations throughout South Africa with the deployment of Xpert mobile laboratories to provide on-site molecular diagnostic TB testing. As part of the planning processes, NPP staff would attend all plenary planning meetings with DoH and NHLS' regional management.

Output

The commemorations of both national World TB Day 2020 and World AIDS Day 2021 were cancelled due to the COVID-19 pandemic over fears that gatherings may constitute SARS-CoV-2 super-spreading events.

LINKAGE-TO-CARE AND DATA MANAGEMENT FOR PROGRAMMATIC MONITORING

National Laboratory Results SMS Printer Programme

Overview

The NHLS SMS printer rapidly delivers HIV- and TB-related results upon authorisation, including CD4 counts, reflexed CrAg, HIV VL, EID PCR, TB smear microscopy, Xpert MTB/RIF Ultra, any amended results from those listed, and notifications of rejected specimens. The printers are placed at healthcare facilities that initiate patients on ART treatment.

The SMS printers operate bi-directionally. Patient results can thus be retrieved when healthcare workers scan the respective NHLS barcodes. The bi-directionality aims to improve the rapid delivery of priority diagnostic results throughout South Africa.

Operations and output

The following improvements were implemented in 2020/21:

A transition was made from SMS to Global Data Services Platform (GDSP) to improve network connectivity. The transition was completed for 75.5% of existing printers.

- Due to the fact that it does not have the character and cost limitations of SMS, the transitioning to GDSP also enabled the addition of extra test results to the existing test repertoire. This allowed creatinine, glomerular filtration rate estimates, and hepatitis B surface antigen results to be included.

The monitoring dashboard, established in 2019/20, continued to provide the following:

- regular reports to business units and DoH-approved healthcare professionals; and
- notifications of facilities with non-functional printers to enable interventions.

During 2020/21, 7 466 190 results were successfully delivered to healthcare facilities through this mechanism. As a further improvement, turnaround time monitoring for result delivery will be implemented in the last quarter of 2021.

Data management for programmatic monitoring

Overview

During 2020/21, analysis of data for programmatic monitoring and evaluation purposes continued in compliance with ethics requirements under the Wits Human Research Ethics Committee, Clearance M160978. The scope included the generation of an array of monthly, quarterly and ad-hoc reports for distribution to partners, funders, DoH TB/HIV coordinators, and provincial and national departments of health. The reports provide aggregated/non-patient identified data on test volumes, detection rates, turnaround times, error rates, specimen rejection rates and exception reporting such as tests with CD4 counts under 100 cells/µl and HIV VL counts of under 1 000 copies/ml. Programmatically, data was used to analyse laboratory workflow and monitor instrument utilisation rates. Stakeholders utilise information such as rejection rates to design training interventions that serve to correct these issues. The correlation of detection rates or positivity rates for TB are utilised to confer numbers reported in TB registers and assist in reducing the number of patients lost to follow up.

Output

Xpert MTB/RIF and Xpert MTB/RIF Ultra operational dashboard

In addition to the programmatic monitoring and evaluation reports (detailed above) an Xpert MTB/RIF and Xpert MTB/RIF Ultra operational (test-based) dashboard was developed. The dashboard was created in alignment with the existing HIV dashboard currently hosted by the National Institute for Communicable Diseases (NICD) Statistical Data Warehouse (SDW). Xpert dashboard development was completed by the BiTanium group, funded though the Newton Fund/Medical Research Council. The dashboard has collated all Xpert MTB/RIF and Xpert MTB/RIF Ultra data, since programme inception, into two groups:

- geographic distribution dashboard; and
- national and indicator trends dashboard.

The geographic distribution dashboard displays Xpert MTB/RIF and MTB/RIF Ultra data according to the following:

- results, positivity rate, resistance rates;
- year, quarter, month;
- age;
- specimen type (pulmonary, extra-pulmonary or unspecified); and
- national, provincial, district.

The national and indicator trends dashboard displays Xpert MTB/RIF and MTB/RIF Ultra data according to the following:

- indicator (test result, positivity and resistance data) distribution by sex and age group;
- indicator trends for the previous 12 months; and
- indicator trends nationally, by province, district, sub-district and facility.

Working with CDW colleagues and business intelligence counterparts, dashboards were extensively tested and data quality controlled. Following sign-off, dashboards were migrated into the CDW production environment. The establishment of a dashboard access programme and custodianship, in line with CDW requirements, will be completed in Quarter 1 of 2021/22, with the aim of officially launching the dashboard later in 2021.

RESEARCH AND DEVELOPMENT TO SUPPORT THE NATIONAL PROGRAMMES

Overview

The NPP Research and Development (R&D) Group comprises a multidisciplinary team specialising in applied research and the implementation of new laboratory diagnostics for HIV, TB and COVID-19, and includes quality management systems of high- to low-throughput testing platforms. The R&D Group also includes specialists in data science, digital health and GIS mapping. Under the leadership of Prof Lesley Scott, the Group's outputs have contributed to the following:

- improvement of services within the NHLS, and within the context of COVID-19. This included collaborating with SAHPRA for COVID-19 assay evaluations for recommendations on in-country licensing;
- transfer of knowledge and implementation support to the NPP;
- policy development for the DoH; and
- global quality management for several diagnostic tests.

A key focus of the R&D Group is innovation within the laboratory value chain, spearheaded through Innovation in Laboratory Engineered Accelerated Diagnostics (iLEAD), which was established within the R&D Group in late 2017 through seed funding from the Bill and Melinda Gates Foundation. The portfolio of iLEAD comprises several innovations at various phases of development, and ranges from technologies with incremental innovation to those that are disruptive game-changers. The primary work streams in the iLEAD portfolio are HIV, TB, COVID-19 and cross-cutting innovations that fall within the digital health space and are used across the laboratory value chain. The R&D team are also supported by National Institutes of Health (NIH) and the South African Medical Research Council (SAMRC) funding for innovations in TB diagnostics and data science for impact.

Output

Contributing to Africa's innovation through science: Verification and external quality assurance programmes

- ***Xpert MTB/RIF EQA and Verification Programme:*** The R&D team continued to engage and provide scientific and technical support to SmartSpot Quality (Pty) Ltd, a Wits Enterprise spin-off company initiated from the R&D Group. National and international laboratories are supplied with DCS technology for verification and EQA of the Xpert MTB/RIF Ultra (Cepheid, Sunnyvale, CA, USA) platform. The MTB Combo EQA Programme comprises the GenoType MTBDRplus and GenoType MTBDRsl (Bruker-HAIN diagnostics, Nehren, Germany) EQA and the Strip Interprettion Analysis programmes.
- ***MTB LAM EQA:*** The R&D team is developing a quality material and programme to support the testing of lipoarabinomannan (LAM) in both clinical (point-of-care) and laboratory settings, with funding support from the University of the Witwatersrand (the R&D Group was awarded a Biomedical Innovation Award, managed through Wits Enterprise).
- ***HIV Viral Load Programmes:*** The HIV VL thermostable EQA material developed by the team continues to be supplied by SmartSpot Quality (Pty) Ltd through technology transfer. The underlying technology and pilot study have been published[28].

- ***SARS-CoV-2 Reference Material for GeneXpert:*** The European Commission Joint Research Centre EURM-019 supplied reference materials to the NPP for distribution to routine laboratories in South Africa to assess SARS-CoV-2 assay performance. The team oversaw this process, with all ten participating laboratories achieving scores of 100%. The team collaborated with Prof Bavesh Kana from the Department of Science and Innovation (DSI)/National Research Foundation (NRF) Centre of Excellence for Biomedical TB Research to evaluate biomimetics and the SARS-CoV-2 viral culture to standardise the evaluation of SARS-CoV-2 molecular tests under review, by the team, for SAHPRA and in collaboration with several in-country assay developers.

Contributing to national health TB policy: Aiming for improvements in sensitivity of TB molecular diagnostics

- ***Xpert XDR:*** A multi-centre clinical trial, in collaboration with the Foundation for Innovative New Diagnostics (FIND), was performed in the Eastern Cape to evaluate the novel Xpert XDR cartridge (Cepheid, Sunnyvale, CA, USA) that detects further TB drug-resistance targets. This trial completed participant enrolment in July 2019 and contributed to the WHO policy on molecular diagnostics. A draft manuscript is being reviewed by co-authors for journal submission.
- ***Molecular TB multiplatform evaluation:*** A head-to-head evaluation of multiple molecular assays for TB diagnosis (in collaboration with FIND and WHO) was performed to investigate the limit of detection and precision of multiple molecular TB assays [Roche MTB (Roche Molecular, Pleasanton, CA, USA), Hain Fluorotype MTB RIF/INH (Brucker-Hain Diagnostics, Nehren, Germany), Abbott RT MTB and MTB RIF/INH (Abbott Molecular, Abbott Park, IL, USA), BD MAX™ MDR-TB (Franklin Lakes, NJ, USA) and Xpert MTB/RIF (Cepheid, Sunnyvale, CA, USA]. The evaluation has been ongoing since 2018 and comprised of two phases:
  - Phase 1 (laboratory strain analytical evaluation) was completed and a report circulated to the NPP
  - Phase 2 has commenced with only Roche MTB and Hain Fluorotype assays in comparison to SOC (Xpert MTB/RIF Ultra) and continued into 2020

The study was halted during the COVID-19 pandemic (24 March to 26 August 2020), but resumed with participant enrolment expected to be completed by April 2021. Initial findings have been published [29,30,31].

- ***MTBC-positive culture Microbank:*** In 2020/21, Mycobacterium tuberculosis complex (MTBC)-positive isolates with varying mutation patterns continue to be processed for long-term storage at -80°C. A collaboration was initiated with the NHLS Port Elizabeth's TB culture laboratory to expand the numbers of relevant strains available for research. A manuscript detailing the storage procedure is under journal review.
- ***Xpert host response assay evaluation:*** The Xpert TB host response assay is an in-vitro RT-PCR assay for the detection of a specific human host response in individuals with suspicion of active M. tuberculosis infection, from human capillary finger stick or venous ethylenediaminetetraacetic acid (EDTA) whole blood. A clinical evaluation of the cartridge is being performed in collaboration with Cepheid. The study began in December 2020 and is ongoing.

Contributing to national health TB policy: Information technology's superpower and its place in global disease control

- ***Molecular TB linked to geographic information system (GIS) mapping:*** The following two geospatial TB mapping projects are ongoing:
  - NIH (R21)-funded GIS TB mapping to evaluate the use of Xpert MTB/RIF and Xpert MTB/RIF Ultra cycle threshold values in collaboration with Boston University
  - A Newton Fund/Medical Research Council/South Africa/United Kingdom-funded project to investigate the mapping of molecular characteristics from the Xpert MTB/RIF Ultra assay across districts in South Africa, in collaboration with the University of the Witwatersrand's School of Public Health, the London School of Hygiene and Tropical Medicine, Boston University and BiTanium.

[28] Noble LD, Scott LE, Bongwe A, Da Silva P, Stevens WS. The development of a standardised quality assessment material to support Xpert® HIV-1 viral load testing for ART monitoring in South Africa. Diagnostics (Basel). Published online 22 Jan 2021;11(2):160. DOI: 10.3390/diagnostics11020160. PMID: 33499162.
[29] De Vos M, Scott L, David A, Trollip A, Hoffmann H, Georghiou S, Carmona S, Ruhwald M, Stevens W, Denkinger CM, Schumacher SG. Comparative analytical evaluation of four centralized platforms for the detection of M. tuberculosis complex and resistance to rifampicin and isoniazid. Journal of Clinical Microbiology. Published online ahead of print 2 December 2020;02168-20. DOI: 10.1128/JCM.02168-20. PMID: 33268535.
[30] David A, Singh L, Da Silva P, Scott L, Stevens W. The performance of the Abbott real-time MTB RIF/INH compared to the MTBDRplus V2 for the identification of MDR-TB among isolates. Infection and Drug Resistance. Published online ahead of print 28 September 2020;13:3301-3308. DOI: 10.2147/IDR.S247524. eCollection 2020. PMID: 33061477.
[31] Scott L, David A, Govender L, Furrer J, Rakgokong M, Waja Z, Martinson N, Eisenberg G, Marlowe E, Stevens W. Performance of the Roche cobas MTB assay for the molecular diagnosis of pulmonary tuberculosis in a high HIV burden setting. Journal of Molecular Diagnostics. 2020;22(10):1225-1237. DOI: 10.1016/j.jmoldx.2020.06.018. Epub 1 August 2020. PMID: 32745613.

Additional projects linked to GIS mapping work include the following:

- Data analysis of 62 clinics in the Eastern Cape to determine the use of cycle threshold (bacterial burden) to determine TB and rifampicin-resistance hotspots (ongoing analysis)
- Data analysis of Xpert MTB/RIF Ultra "trace" specimens to determine laboratory outcomes for patients diagnosed with "trace" (manuscript under co-author review)
- Temporal spatial analytics applied to drug-resistant TB to investigate the association between MTBDRplus version 2 assay missing wild type probes and corresponding Xpert probes (piloted in the North West and extended to Gauteng with manuscript accepted for publication)
- National Xpert MTB/RIF and Xpert MTB/RIF Ultra dashboard development (previously discussed)

- ***Longitudinal TB-cohort:*** The R&D team continued to assist the data analytics team of the NPP and collaborate on the development and integration of an algorithm developed by Dr Jacob Bor (Boston University, Boston, MA, USA) to uniquely identify patients over time using record linkage to create a longitudinal TB cohort. The same group had developed the NHLS' HIV longitudinal cohort. The aim is to then integrate both the HIV and TB longitudinal cohorts.
- ***TB Think Tank – New Tools Group:*** The R&D team, together with key NPP staff, joined the DoH's TB Think Tank. The New Tools Sub-group provides guidance on new TB diagnostic tools.

Contributing to improved HIV testing and monitoring services

- ***Plasma Separation Card (PSC):*** The PSC (Roche Molecular, Pleasanton, CA, USA) is an alternative plasma specimen collection device that eliminates the need for phlebotomy and provides stable specimen transport, thereby increasing access to accurate HIV VL testing. The multisite national clinical evaluation, in collaboration with Dr Diana Hardie (NHLS Groote Schuur, Cape Town) was cancelled due to the COVID-19 pandemic.

  The R&D team completed evaluations of the PSC for HIV VL testing on alternative HIV VL platforms, with 90% sensitivity and 65% specificity reported on the Abbott m2000 platform (91 specimens) and only limited specimens (14) tested on the GeneXpert (75% sensitivity, 100% specificity). Findings have been published[32]. Alternative plasma separator devices also showed limited sensitivity and specificity, and data analysis is still under review.

  The following alternative use cases for the PSC (beyond HIV VL) were also examined:

  - A therapeutic drug monitoring study was performed in collaboration with Prof Jaya George (Department of Chemical Pathology, University of the Witwatersrand, Johannesburg) (results pending).
  - An HIV genotyping evaluation was initiated in collaboration with Dr Kim Steegen (NHLS HIV Drug Resistance Laboratory, CMJAH) with results (35 specimens) indicating that the PSC, lysed using a two-hour method, is a suitable alternative to plasma for HIV-1 drug-resistance testing.
  - The use of PSC for COVID-19 serology testing (EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) assay) was evaluated in collaboration with Prof Elizabeth Mayne (Department of Immunology, University of the Witwatersrand) with limited specimens tested (sensitivity ranging from 50% (day 11–20) to 91% (day 31–50) and 100% specificity).

  The third use case was not recommended further.

Addressing the COVID-19 pandemic – SARS-CoV-2 diagnostic evaluations

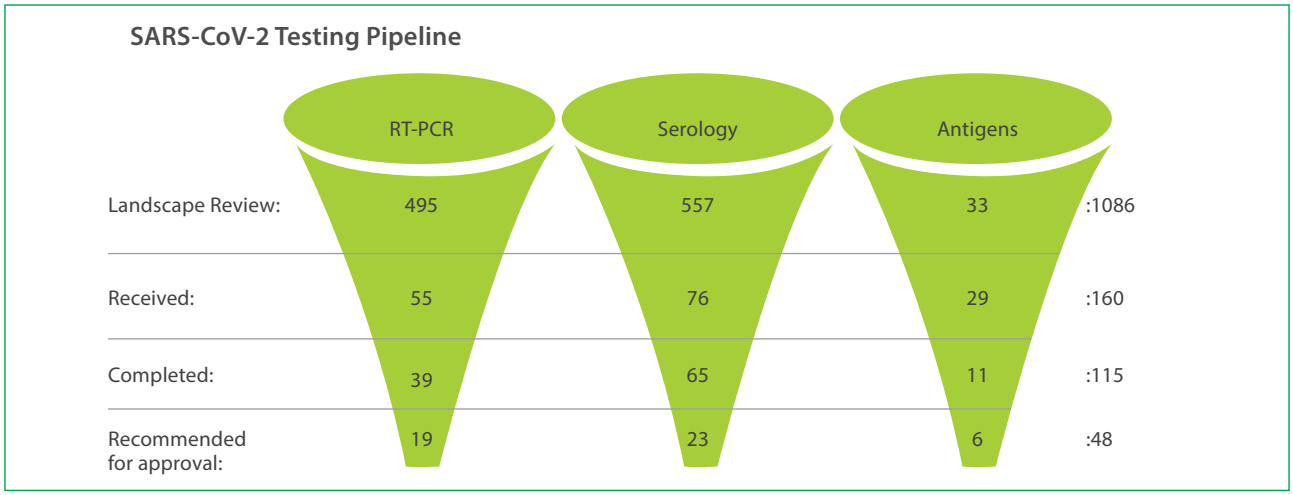
Since April 2020, the R&D Group has evaluated SARS-CoV-2 diagnostics (molecular, serology and antigen), performed through iLEAD in collaboration with the NPP and SAHPRA. This research was funded by the Bill and Melinda Gates Foundation.

SARS-CoV-2 cultures continued to be provided through collaboration with Prof Bavesh Kana (Centre of Excellence for Biomedical TB Research, Johannesburg), including more recent SARS-CoV-2 variant cultures. Residual patient specimens were also used to evaluate novel assays, with the standard of care molecular result used as reference. In 2020/21, of the 1 086 assays included in landscape reviews, 160 were received for evaluation, with 115 of these evaluated. Forty-eight were recommended for use (see Figure NPP12).

[32] Vubil A, Zicai AF, Sitoe N, Nhachigule C, Meggi B, Loquiha O, Viegas S, Mabunda N, Scott L, Jani I. Accurate HIV viral load measurement in primary healthcare settings using the cobas® plasma separation card. PLoS One. 2020;15(5):e0232122. DOI: 10.1371/journal.pone.0232122. eCollection 2020. PMID:32374748.

In addition, multiple collection swabs and transport/elution media were assessed by the team, with recommendations shared with the NPP and published[33] (see Figure 13/NPP13). The R&D Group continued to provide support for the laboratories performing SARS-CoV-2, rapid antigen and COVID-19[34, 35,] antibody testing· (see Figure NPP14).

Figure NPP12: SARS-CoV-2 test evaluation pipeline, 2020/21



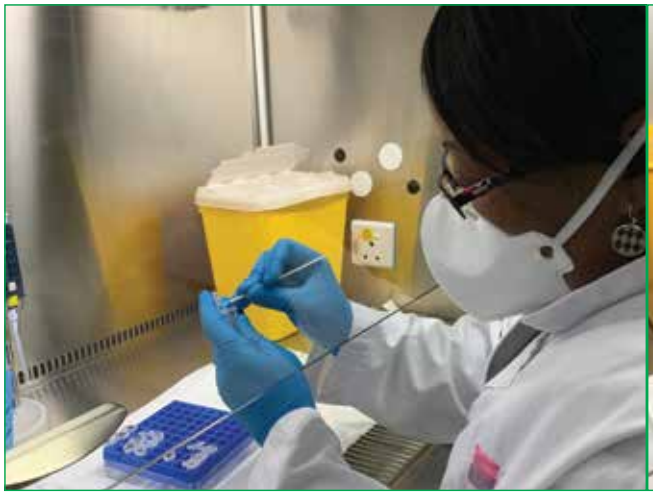


Figure NPP13: Trish Kahamba (medical scientist) evaluating collection swab absorption for SARS-CoV-2 diagnosis

Figure NPP14: Dr Vidya Keshav (medical scientist and PhD candidate) evaluating SARS-COV-2 rapid-antigen assays

Data analytics for continuous quality monitoring and epidemiology of COVID-19

The R&D data team leveraged its TB data analytics skills and applied these to COVID-19 data for continuous quality monitoring of laboratory diagnostics, funded by the SAMRC. The cycle threshold, a continuous variable of PCR tests, was used as an added epidemiology marker. Data updates were shared with the Virology Expert Committee and nationally through various partners (see Figure NPP15). GIS mapping between COVID-19, HIV and TB diagnostic variables continued to support NPP with operations (see Figure NPP16).

33] Kahamba T, Noble L, Scott L, Stevens W. Comparison of three nasopharyngeal swab types and the impact of physiochemical properties for optimal SARS-CoV-2 detection. https://www.longdom.org/open-access/comparison-of-three-nasopharyngeal-swab-types-and-the-impact-of-physiochemical-properties-for-optimal-sarscov2-detection.pdf.
[34] Mayne ES, Scott L, Semete B, Julsing A, Jugwanth S, Mampeule N, David A, Gededzha MP, Goga A, Hardie D, Preiser W, Chetty K, Rees H, Sanne I, Mlisana K, George JA, Stevens W. The role of serological testing in the SARS-CoV-2 outbreak. South African Medical Journal. 2020;110(9):842-845. PMID: 32880264.
[35] Makatsa MS, Tincho MB, Wendoh JM, Ismail SD, Nesamari R, Pera F, De Beer S, David A, Jugwanth S, Gededzha MP, Mampeule N, Sanne I, Stevens W, Scott L, Blackburn J, Mayne ES, Keeton RS, Burgers WA. SARS-CoV-2 antigens expressed in plants detect antibody responses in COVID-19 patients. Frontiers of Plant Science. 2021;12:589940.

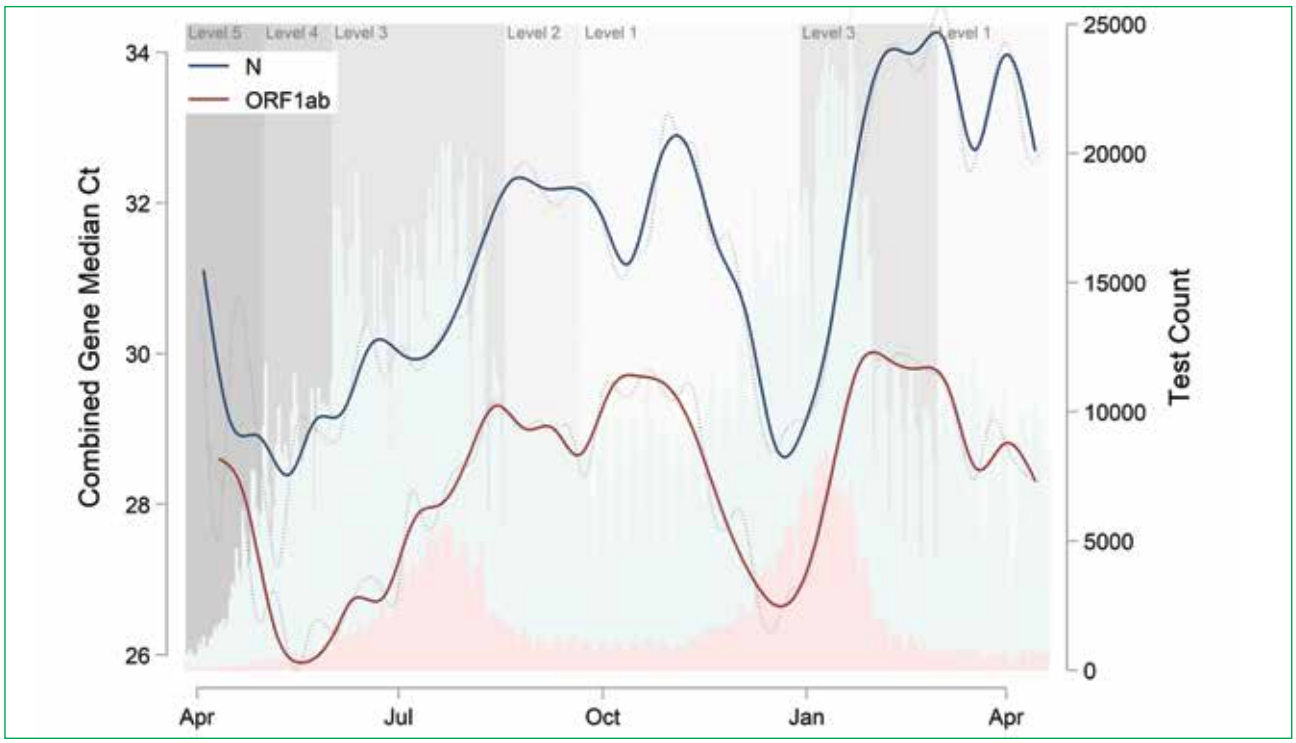


Figure NPP15: Combined median N gene Ct values from Allplex™ SARS-CoV-2; TaqPath™ COVID-19 and Xpert Xpress SARS-CoV-2 and combined median Orf-1ab gene cycle threshold values from TaqPath™ COVID-19 and Cobas SARS-CoV-2 assays. The navy solid line reflects the rolling average of the combined N gene median cycle threshold and the maroon solid line reflects the rolling average of the combined Orf1ab gene median cycle threshold.

Figure NPP16: Silence Ndlovu (NPP data analyst) tracking SARS-CoV-2, HIV, and TB data to support continuous quality monitoring Improving the laboratory value chain: leveraging digital technology.

Members of the team provided scientific support to several digital health technology projects, either directly managed through the NPP or through grant-funded projects.

- ***eLABS:*** eLABS (an electronic laboratory specimen tracking tool) was initially developed for scaled HIV VL testing in Zambia. At the end of March 2021, eLABS had been scaled to 885 facilities in Zambia and 1 588 facilities across South Africa, with over 685 000 VL tests processed in Zambia and 1.79 million in South Africa. Of the processed tests, 91% and 98% were authorised in Zambia and South Africa, respectively. The average result turnaround time was 23 days in Zambia and two days in South Africa. The HIV VL suppression was 89% in Zambia and 87% in South Africa. Some 85% of actionable results (unsuppressed patients) were read by the healthcare workers in Zambia and 68% in South Africa. On 24 July 2020, eLABS rolled out its COVID-19 module in South Africa to support the SARS-CoV-2 pandemic. To date, over 445 000 RT-PCR tests have been processed through eLABS with a 20% positivity rate. The SARS-CoV-2 antigen rapid diagnostic test module has subsequently been developed to support the point-of-testing sites in South Africa. This module is due to be implemented in May 2021. eLABS is now being piloted in Mozambique (in Portuguese) and Nigeria, with Liberia to follow suit. Further details are included under the CDC-grant funded activities section.

- ***CASSPer:*** In collaboration with the Bill and Melinda Gates Foundation, Ezintsha, Clinical HIV Research Unit, Clinical Laboratory Services and Praekelt, an application to support COVID-19 self-sampling for healthcare workers was piloted at the Helen Joseph Hospital and CMJAH. A critical component of self-sampling is the validation of an end-to-end digital pathway for the client. The application is still in its infancy (minimum viable product) and its current functionality supports the RT-PCR testing algorithm, symptom screening and risk identification, specimen collection and demographic information, and result delivery to the healthcare worker. The application validation analysis will be conducted at the end of the study (ending in May 2021).
- ***Digital Health Policy:*** Digital health requires an easy-to-use business intelligence system, an overall secure digital health functionality ensuring data security and patient confidentiality, and impact studies to be performed. To address some of these, Prof Wendy Stevens and partners drafted a digital health policy. The policy was updated and circulated to the NHLS executive for further input. The main focus of the policy is to identify the layers that affect data security and privacy/ confidentiality throughout the data life cycle.

Publications

Based on R&D activties in 2020/21, eight publications were published in peer-reviewed journals, five as first author (detailed above). For activities completed in 2019/20, an additional two publications were accepted in 2020/021: an evaluation of the Fio Deki Reader for rapid HIV result interpretation[36] (first author); and discordance between molecular assays for rifampicin resistance detection in *M. tuberculosis*[37].

Accepted abstract presentations included one at the 51st World Conference on Lung Health of the International Union Against Tuberculosis and Lung Disease, held virtually from 20 to 24 October 2020[38], and three presented virtually at INTEREST 2020, 30 November to 4 December 2020[39, 40, 41].

Presentation contributions at eight SARS-CoV-2 diagnostic virtual webinars were held in 2020/21 with various partners: NHLS (19 May and 10 June 2020), Virology Expert Committee (23 July, 27 July and 10 August 2020), SAHPRA/SAMRC (16 July 2020), CDC (25 June 2020) and 501Y-Variant Working Group (8 February 2021). Presentations focused on continuous quality improvement for SARS-CoV-2 diagnostics, diagnostic complexities and laboratory preparedness.

ADDITIONAL ACTIVITIES TO SUPPORT THE NATIONAL PROGRAMMES

Centers for Disease Control-funded activities

Overview

The Cooperative Agreement (6 NU2GGH001934-04-07) was awarded in 2019 and the implementation of the programme was executed through the NPP for HIV VL support focusing on 27 PEPFAR-supported districts in South Africa. This activity was previously awarded under a cooperative agreement with the NHLS (CoAg 5 NU2GGH001631-04-00) in 2015. The overarching goal of the funding is to strengthen the clinic-laboratory-patient interface and improve access to HIV VL monitoring.

[36] Noble L, Scott L, Stewart-Isherwood L, Molifi SJ, Sanne I, Da Silva P, Stevens W. Continuous quality monitoring in the field: An evaluation of the performance of the Fio Deki Reader for rapid HIV testing in South Africa. BMC Infectious Diseases. 2020;20(1):320. DOI: 10.1186/s12879-020-4932-0.
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Subprojects

Improving the laboratory value chain – leveraging digital technology: eLABS

eLABS (an electronic laboratory specimen tracking tool) was initially developed for scaled HIV VL testing in Zambia and is currently being expanded to a number of countries. eLABS-South Africa was previously piloted through the NHLS at 24 facilities in Gauteng.

Key indicators of the project are the following:

- improvement in turnaround times;
- reduction in specimen rejection rates; and
- increase the rate of HIV VL result acknowledgement by healthcare facilities.

The COVID-19 pandemic resulted in the accelerated development of the eLABS application to accommodate challenges that were faced at the time:

- development of the system adoption dashboard to enable views of facilities actively utilising the eLABS application, i.e. in the previous 7, 14, 21 days, etc. (this module went live in March 2020 and was useful when providing remote support);
- development of the onboarding module allowing for the automation of registering users (the module went live on 27 May 2020); and
- development of the COVID-19 module (launched on 24 July 2020).

In 2020/2021, 7 886 practitioners were trained on eLABS. The use of the eLABS application had been expanded to 1 588 facilities across more than 20 districts in six provinces:

- 620 in the Eastern Cape
- 117 in the Free State
- 100 in Gauteng
- 185 in KwaZulu-Natal
- 299 in Mpumalanga
- 267 in North West

By March 2021, 13 867 registered facility users and 73 registered courier services across six provinces were noted. In 2020/21, more than 3.9 million barcodes had been scanned via the application, with 48% representing HIV VL requests. Of HIV VL requests, 98% were tested and results authorised, with 87% representative of viral suppression. Of all actionable results (patients requiring repeat phlebotomy and those with HIV VL over 1 000 copies/ml), 68% were acknowledged by healthcare workers.

HIV viral load support

Acceleration of optimised HIV testing is critical in attaining the UNAIDS 95-95-95 targets. Some 419 Siyenza PEPFAR-supported facilities and 16 HIV VL testing laboratories were earmarked to receive support from technical and clinical HIV VL trainers to strengthen the clinic-laboratory interface.

Technical trainers conducted baseline and workflow assessments at facility and testing laboratory levels to identify gaps that were impacting on the efficiency of the clinic-laboratory interface. These assessments informed improvement plans to increase efficiency, improve turnaround times and minimise rejection rates. Ongoing support was provided in 2020/21, despite the COVID-19 pandemic, with 212 healthcare facilities supported. With the introduction of SARS-CoV-2 testing across NHLS laboratories and the use of HIV VL testing platforms (Roche and Abbott), technical support was intensified at these testing laboratories.

Real-time laboratory performance monitoring dashboard

This project aimed to provide real-time performance monitoring within the HIV VL NHLS laboratory network through the use of dashboards.

Sixteen HIV VL testing laboratories were earmarked to receive visualisation screens (48 procured) and functional dashboards to monitor processes and improve efficiency. Assessments were conducted at all 16 HIV VL laboratories and installation occurred in tandem with the implementation of the adjudicated NHLS HIV VL tender. The project is set for completion in the next financial year.

Data command centre

Real-time monitoring is used to track performance and improve staff accountability across the service and is not uncommon among private pathology groups. The data command centre provides real-time performance monitoring within the HIV VL NHLS laboratory network through the use of visual dashboards, with the aim of strengthening the laboratory quality and diagnostic services to both facilities and patients. The command centre went live in April 2020 and includes a call centre for queries. The plan is to include additional priority tests (other than HIV VL).

ASLM COVID-19 Antigen Rapid Diagnostic Testing Training Programme

Overview

SARS-CoV-2 antigen rapid diagnostic tests (RDTs) are an alternative to the more complex PCR assays, are simpler to use and provide a point-of-care testing solution, thereby increasing testing capacity and decongesting centralised testing laboratories. Antigen RDTs have revolutionised the response to COVID-19 by providing accurate test results within 30 minutes, instead of days, and dramatically lowering the price of testing. However, proper training on the safe use and implementation of antigen RDTs is vital to ensure high-quality testing. The ASLM developed a comprehensive training package, which was implemented in South Africa in partnership with the NPP, under the NHLS. The training modules include the following:

- safety;
- specimen collection;
- performance of COVID-19 antigen RDT testing;
- reporting and management of the COVID-19 antigen RDT test results; and
- quality assurance.

The training modules were packaged to ensure standardisation across the African continent as per WHO guidelines.

Operations

Preparations and implementation of the antigen RDT training programme included the following:

- training of 23 COVID-19 antigen RDT master trainers by ASLM, 21–22 January 2021;
- review of all training modules and material by master trainers to model the training package for the South African context (including testing algorithm and the application of both Abbott Panbio and Standard Q RDT kits);
- nomination of NHLS training leads to spearhead training by DoH;
- with support from the NHLS' Monitoring and Evaluation office, nominations for trainer-of-the trainers' course were submitted by area and business managers; and
- Provision of training to end-users in three-hour sessions.

The training course included two practical activities for specimen collection, four practical activities to demonstrate COVID-19 antigen RDT testing and a theory assessment. Certification was successful if 100% attendance was achieved for all training modules, with a 100% pass rate on practical activities and a score above 80% for theory assessments. The course was also accredited by the University of the Witwatersrand for continuing professional development points. Subsequent supervision visits were conducted to ensure that high standards of quality training for COVID-19 antigen RDT are maintained in South Africa.

Output

Training

Between February and March 2021, 398 delegates attended training with 82% receiving ASLM certification. End-user training required strict adherence to COVID-19 health and safety guidelines with large venues sought to meet social distancing regulations. Table NPP1 details ASLM certifications for the trainer-of-the-trainers' course and Table NPP2 details the end-user course activities.

Table NPP1: COVID-19 antigen RDT trainer-of-the trainers' course activities, February to March 2021

Training dates	Province	Number of attendees	Number of ASLM certifications
5-6 February 2021	Mpumalanga	13	13
12-13 February 2021	KwaZulu-Natal	18	13
19-20 February 2021	Free State/North West	35	24
25-26 February 2021	Gauteng	82	52
11-12 March 2021	General	34	21
Total		**182**	**123**

Table NPP2: COVID-19 antigen RDT end-user course activities

Training dates	Province	Number of attendees	Number of ASLM certifications
24 March 2021	Brakpan, Ekurhuleni	32	32
25 March 2021	Kempton Park, Ekurhuleni	40	40
25 March 2021	Eshowe, KwaZulu-Natal	18	14
26 March 2021	Alberton, Ekurhuleni	42	40
26 March 2021	Prince Street, KwaZulu-Natal	11	11
28 March 2021	South Rand Hospital	19	14
29 March 2021	Inanda	10	9
30 March 2021	Inanda	8	8
31 March 2021	Phoenix Community Health Centre	36	35
Total		**216**	**203**

Planned activities under the antigen RDT training include the following:

- development of an ethics module;
- identification of additional master trainers;
- provision and enrolment in the ASLM proficiency testing scheme for COVID-19 antigen RDT for all testing sites; and
- enrolment of all COVID-19 antigen RDT testing sites in an EQA programme currently under development by the NHLS' Quality Assurance division.

Figure NPP17: KwaZulu-Natal (eThekwini business unit) SARS-CoV-2 rapid antigen testing training with Nompumelelo Phakathi and Sithandiwe Ngubane demonstrating the collection of nasopharyngeal swabs

Figure NPP18: Gauteng (Ekurhuleni district) training with end-users practicing SARS-COV-2 rapid antigen testing

Figure NPP19: Phlebotomist demonstrating SARS-COV-2 rapid antigen testing to end-users at the Brakpan Civic Centre

2.4.3 Academic Affairs, Research and Quality Assurance

Prof Koleka Mlisana
Executive Manager

Introduction

The main objectives of the Academic Affairs, Research and Quality Assurance (AARQA) department of the NHLS are to strengthen the academic affairs, teaching and training, as well as the research and innovation mandate of the organisation while maintaining and providing quality improvement processes throughout the platform. AARQA comprises two units, namely: Academic Affairs and Research (AAR), and Quality Assurance (QA), which are collectively responsible for overseeing the implementation and management of the NHLS aligned strategic and operational mandate of the division, nationally.

AARQA is responsible for the maintenance and establishment of effective partnerships with faculties of health sciences across South African medical universities, comprehensive universities (CUs) and universities of technology (UoTs).

In collaboration with the area managers, the department also serves to do the following:

- enhance the NHLS QA systems and processes;
- maintain and acquire accreditation of the laboratories across the country; and
- manage the proficiency testing schemes (PTSs) for all NHLS laboratories, private pathology laboratories and other African laboratories.

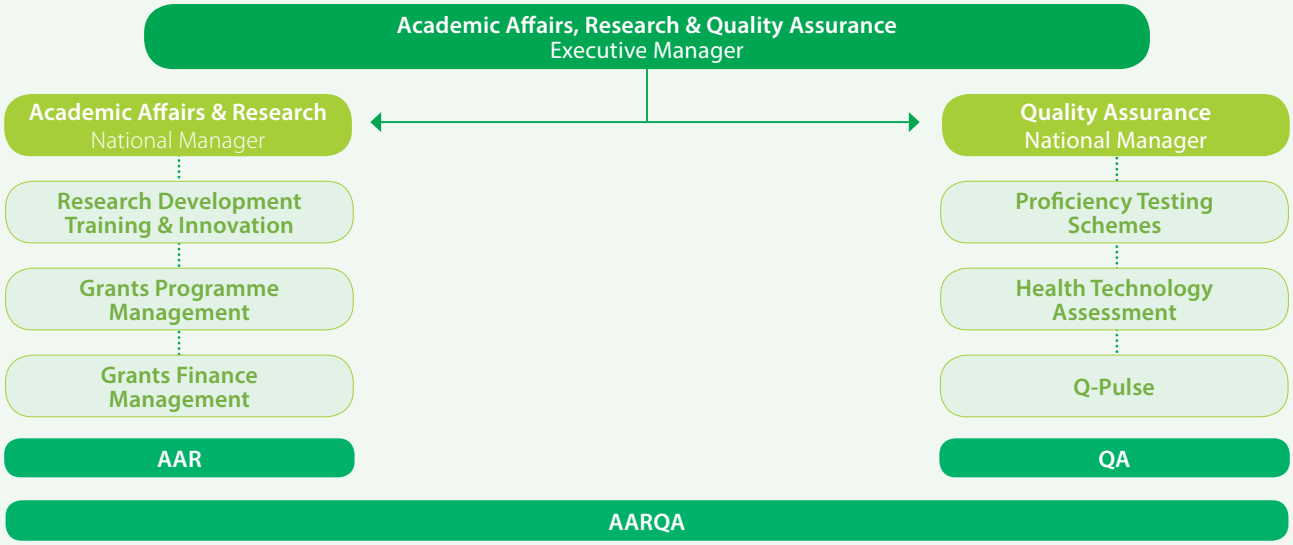


Figure 1: AARQA Management organogram and units

Academic Affairs and Research Department

The Academic Affairs and Research (AAR) Unit is responsible for the teaching, training and research mandate of the NHLS. In collaboration with the medical universities, comprehensive universities and universities of technology, the department supports an academic platform staffed with skilled personnel that provide technical pathology training.

The training output and laboratory services are provided by skilled pathologists and medical scientists, technologists and technicians. The office provides support for research and innovative activities that are mainly undertaken in partnership with the academic institutions; with the aim of ensuring cutting-edge yet locally responsive research with an emphasised focus on translational research to enhance the service platform, influence health policy and improve public health.

Figure 2: Medical universities in partnership with the NHLS

Figure 3: Universities of technology and comprehensive universities in partnership with the NHLS

The Unit is also responsible for overseeing the management and support of the implementation, monitoring and evaluation of the research strategic initiatives of the NHLS and the financial administration and management of grant-funded projects within the organisation. The department consists of the following three offices:

- Research Development Training and Innovation;
- Grants Programme Management; and
- Grants Finance Management.

Research, Development and Innovation

Teaching and training

The delivery of the teaching, training and research mandate of the NHLS is a shared responsibility between the NHLS and the abovementioned universities across South Africa. Vocational training is provided to registrars, intern medical scientists and student medical technologists working towards qualifications as pathologists, medical scientists and technologists, respectively in compliance with the requirements of the Health Professions Council of South Africa (HPCSA).

Table 1: Current NHLS vocational trainees by discipline

Discipline	Intern: medical scientists	Student: medical technologist	Registrar	Total
Anatomical Pathology	3	8	77	88
Chemical Pathology	15	2	36	53
Clinical Pathology		82	13	95
Genetic Counselling	2			2
Haematology	12	3	51	66
Human Genetics	11	1	5	17
Immunology	11	1	1	13
Microbiology	23	5	52	80
Occupational Health	3		3	6
Virology	23	8	21	52
Other		119		119
Total	**103**	**229**	**259**	**591**

During the 2020/2021 financial year, there were 591 trainees from various academic institutions on the NHLS platform. These include 103 medical scientists' interns, 229 medical technology students and 259 registrars. Details on the number of trainees per pathology discipline and the distribution of trainees by academic institutions are shown in tables 1 and 2.

Table 2: NHLS trainees by hosting institution

Institute	Intern: medical scientists	Student: medical technologists	Registrars	All Trainees
Sefako Makgatho Health Sciences University	9	1	26	36
The University of Cape Town	9	1	31	41
University of the Free State	8		19	27
University of KwaZulu-Natal	4		30	34
University of Pretoria	13		38	51
University of Stellenbosch	17		34	51
University of the Witwatersrand	22		76	98
Walter Sisulu University		8	2	10
NICD	14			14
NIOH	7		3	10
NHLS*		219		219
Total	**103**	**229**	**259**	**591**

***Training offered in HPCSA Accredited NHLS laboratories nationally that are not linked to the Academic institutions**.

Registrar and Intern medical scientist pass-rates

The NHLS is the sole provider of training of pathology registrars in the country. To date, the pass rate of registrars, who are trained to be pathologists, has been increasing for the Colleges of Medicine in South Africa (CMSA) Part I examinations from 60% (2018) to 80.7% (2020). Similarly, pass rates CMSA Part II (exit) examinations increased from 40.5% (2018) to 52.6% (2020) as depicted in figure 4.

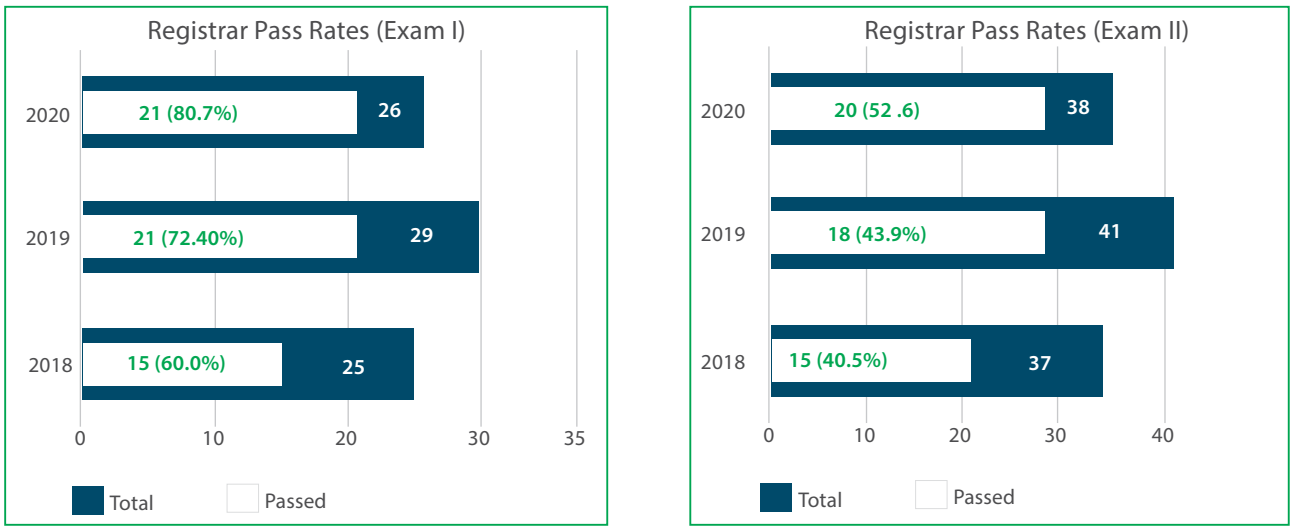


Figure 4: NHLS registrar pass-rates for CMSA examinations semester I and semester II from 2018 to 2020.

The decision by the NHLS executive committee to increase the number of medical scientists' interns trained in the NHLS platforms put the NHLS in a better position to augment its pathology service platform when the unforeseen COVID-19 pandemic hit the country. From April 1998 to March 2021, 101 interns qualified as medical scientists and there was a pool available for placement. In the reported financial year, 70 medical Scientists were certified by the HPCSA by the end of December 2020 (55) and March 2021(15) (**Table 3**).

The NHLS also provides a training platform for intern medical scientists. The HPCSA certified 55 medical scientists in December 2020 and 15 in March 2021.

Table 3: *Intern medical scientists who completed training and were certified by the HPCSA from 2018 to 2021*

Discipline	Year				
	2018	2019	2020	2021	2018 -2021
	Completed	Completed	Completed	Completed	Completed
Anatomical Pathology	2		2		4
Chemical Pathology	3	4	12	3	22
Genetic Counselling	2		2		4
Haematology/Molecular Biology	2	5	11	5	23
Human Genetics	2	3	9		14
Immunology			3	2	5
Medical Microbiology	5		8	4	17
Virology	1	2	8	1	12
Total	**17**	**14**	**55**	**15**	**101**

Project ECHO

In 2018 the NHLS introduced a workforce skills development initiative that utilises the Project Extension for Community Healthcare Outcomes (Project ECHO) zoom video conferencing platform to support the teaching and training platform and enhance diagnostic consultative initiatives. The Project ECHO has been effectively implemented in 86 hubs, spokes, and mini-hub sites at tertiary, regional, and national central laboratories in all nine provinces, as indicated in **figure 5 and 6 below**. This created an expanded and more effective platform for sharing knowledge to help build capacity and develop the skills of pathology and laboratory professionals in laboratory medicine nationwide. Project ECHO enables improved virtual remote access by NHLS trainees, staff and public health professions to specialised teaching and training; Skills development; Interactive lectures and mentoring; consultations and case discussions; and interactive document and report reviews.

The value of the project ECHO is being recognised as we are now noting increases in trainee pass rates and also it contributed to the NHLS rapid response to managing COVID-19 training by linking professionals nationally and allowing continuity of services and rapid roll out of COVID-19 interventions. The training was also expanded to the public health care professionals, emergency services, department of education, post-mortem and funeral service providers for COVID-19 preparedness. NHLS professionals are sharing knowledge on strengthen the pathology service platform.

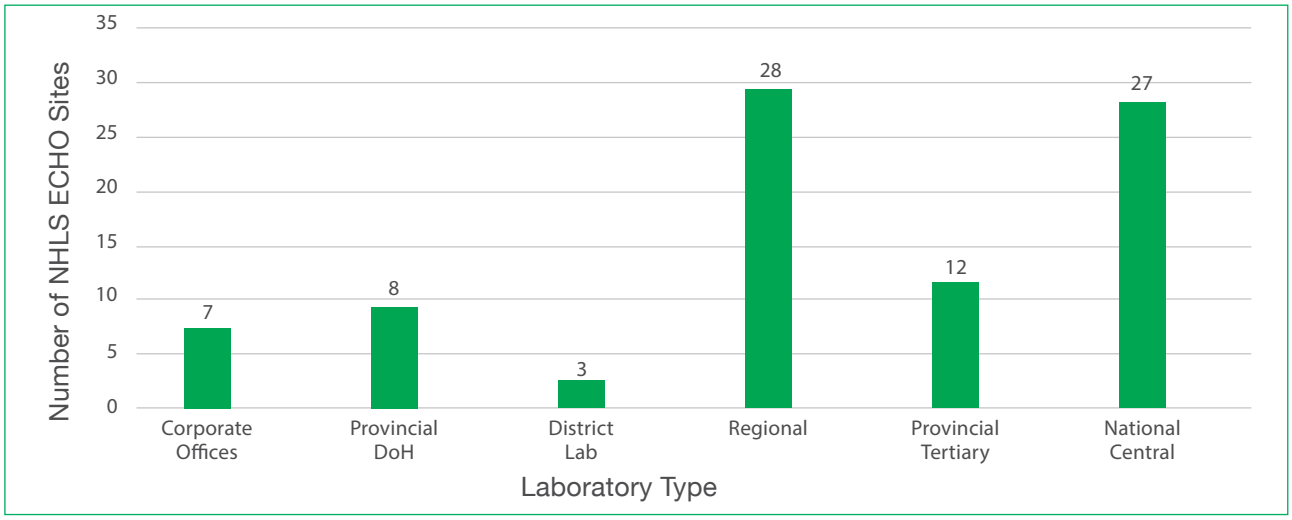


Figure 5: NHLS Project ECHO sites per laboratory type

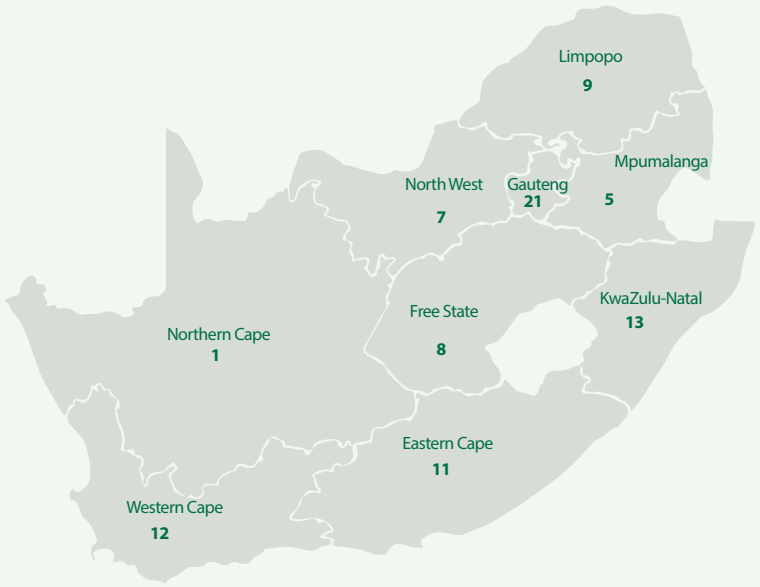


***Figure 6*:** Project ECHO sessions per province

During the 2020/2021 financial period, 619 Project ECHO sessions were conducted, 50.4% of which were discipline-specific sessions (312) presented by subject matter experts, 26% were scientific meetings and 23.6% were NHLS-specific operational sessions (**Table 4**). An average of 101 individual participants attended per session, including registrars, technicians, technologists, medical scientists and intern medical scientists (Table 4 and Figure 5). Public health-related sessions conducted, included the NICD Scientific Forum, South African Field Epidemiology Training Programme, and training for health care workers on COVID-19.

Table 4: NHLS ECHO Programme sessions per discipline and average attendance.

	Anatomical Pathology	Chemical Pathology	Research Development and Innovation	Haematology & Immunology	Human Genetics	Microbiology	Multidisciplinary	Public Health	Scientific Meetings	Operational Sessions	All Sessions*
Apr 2020 – Mar 2021	71	119	5	41	2	20	2	52	161	146	**619**
Attendance per session (Average)	11	9	143	33	80	52	140	507	3	134	**101**
Expert presenters per Discipline	54	78	5	39	3	17	4	72	-	-	**272**

Research support

The NHLS Research and Innovation operational plan was approved and implementation of the key objectives continues. Research development and Innovation sessions are offered via project ECHO. Support is also provided to employees who apply to conduct research using NHLS materials and data. The Research Data Capture (REDCap) system is available for NHLS researchers to use for creating and managing their research databases and surveys.

Scientific Knowledge Centres

In line with the strategic research plan, scientific knowledge centres (SKCs) are in the process of being established. Terms of reference (ToRs) for technical working groups (TWGs) have been drafted and approved, and more TWGs were established during the 2020/21 financial year.

The SKCs will promote innovative research in the key priority areas identified by the NHLS, including TB, HIV, non-communicable diseases.

Bio-specimen and Data Access Requests for Research Purposes

In the financial year from 1 April 2020 up to 31 March 2021, AAR received 272 research project applications, of which 20 were under review and 37 were awaiting amendments by applicants as of 31 March 2021 (Figure 8); 215 applications were finalised (212 Approved and three Rejected). All applications for the full financial year were submitted and reviewed on Academic Affairs and Research Management System (AARMS). The applications include requests for data, samples, and usage of facilities.

Research Publications

A total of 673 journal articles that were co-authored by NHLS researchers were published in indexed journals during the financial year. Information of authorship by the university is indicated below.

Table 5: Number of publications co-authors by NHLS researchers per institution

Institution	Apr 2020 - Mar 2021		
	No of Publications	First Author	Last Author
Sefako Makgatho Health Sciences University	13	8	2
University of the Witwatersrand	213	102	61
The University of Cape Town	112	52	23
University Limpopo	1	0	0
University of Pretoria	53	31	10
University of Stellenbosch	85	36	25
University of the Free State	36	8	4
University of KwaZulu-Natal	53	26	8
University of the Western Cape	7	2	1
Walter Sisulu University	8	1	2
NHLS only	92	33	17
TOTAL	**673**	**299**	**153**

Grants finance management support

The Grants Finance Office (GFO) started its new financial year on 1st of April 2020 with 174 managed projects. At the end of March 2021, there were 281 managed cost centres ending either within the current period or in the future. The GFO is managing a total opening balance of the awarded budget to the value of R452 million of which R207 million (46%) has already been spent leaving an available spending balance of R245 million (54%).

Funds available from top ten grantors as at 31 April 2020

The table below shows that the top ten grantors contribute a total of 91% (R413,2 million) of the total opening budget of R452 million. Other grantors grouped together contribute 9% (R38,8 million) of the total budget. The biggest grantor remains the CDC, which contributes 52% (R236,7 million) of the total funds. Measures to improve the grants processes and ensure that grants are managed efficiently to the satisfaction of all the stakeholders are in progress. The closing budget by the end of March 2021 was 245 million.

Table 6: Top Ten Grantors managed by the grants finance office

Grantors	Opening balance	Total expenditure	Balance available	No of projects	% Budget	% Spent
Centers for Disease Control and Prevention	236,781,899	134,932,957	101,848,942	27	52%	57%
Department of Health	93,528,582	30,290,809	63,237,772	2	21%	32%
NHLS Research Trust	21,686,157	7,631,023	14,055,135	143	5%	35%
The Biovac Institute	14,633,413	118,081	14,515,332	1	3%	1%
Department of Science and Innovation	10,574,083	7,338,909	3,235,174	3	2%	69%
World Health Organization	8,845,426	5,871,543	2,973,883	16	2%	66%
European and developing countries clinical trials partnership	8,154,696	-	8,154,696	1	2%	0%
Wits Health Consortium	7,093,529	174,069	6,919,460	3	2%	2%
African Field Epidemiology Network	6,446,482	235,152	6,211,330	1	1%	4%
Water Research Commission	5,570,852	1,061,715	4,509,136	2	1%	19%
Other	38,773,188	19,388,835	19,384,353	82	9%	50%
TOTAL	**452,088,306**	**207,043,094**	**245,045,213**	**281**	**100%**	**46%**

The NHLS Research Trust

The NHLS Research Trust (NHLSRT) provides research funding opportunities to NHLS researchers across the medical universities within and staff working in the pathology platforms. In the financial year 2020-2021, a total of 78 applications have been received. One percent was for the Research Progression Grant with a maximum award amount of R250 000, and 77 (93%) were for the Development Grant with a maximum award amount of R100 000. The table below details the status of all applications for the NHLS Research Trust:

Table 6: NHLS Research Trust Applications Update

Application status	Development R100 000		Research progression R250 000		All		Grand total
	2020	2021	2020	2021	2020	2021	
Awarded	11	7			11	7	18
Cost Centre Opened	23				23	0	23
Rejected	29	3			30	3	33
Sent for Review			1		0	0	0
Reviewed ¯ Pending NHLSRT Input		4			0	4	4
Grand Total	**63**	**14**	**1**		**64**	**14**	**78**

Quality Assurance Unit

Accreditation and certification

The COVID-19 pandemic had a negative effect on the accreditation and certification progress of the NHLS' laboratories and departments. Pandemic-related restrictions affected training, auditing and coaching for some time until this was replaced by virtual sessions later in the year. Most laboratories and departments had to be closed for some time to decontaminate them and isolate staff members. The majority of the staff had to stop doing the work they normally do and had to concentrate on COVID-19-related work. SANAS was not conducting initial accreditation assessments for the first six months of the financial year. Even though remote assessments were conducted, not all laboratories that applied for accreditation went through initial accreditation as some did not have a stable network connection to allow SANAS to perform remote audits.

Accreditation of medical laboratories ISO 15189:2012

The NHLS continued to increase the number of accredited diagnostic laboratories with 15 new laboratories being accredited during the period under review, compared to 23 in the previous period. At the end of the 2020/21 financial year, there were 91 accredited NHLS laboratories distributed across all nine provinces, 8 in metropolitan and 45 district municipalities (87%), as illustrated in Figure 29. Twenty (22%) of these laboratories were on the Strengthening Laboratory Management Towards Accreditation (SLMTA) quality improvement programme funded by PEPFAR.

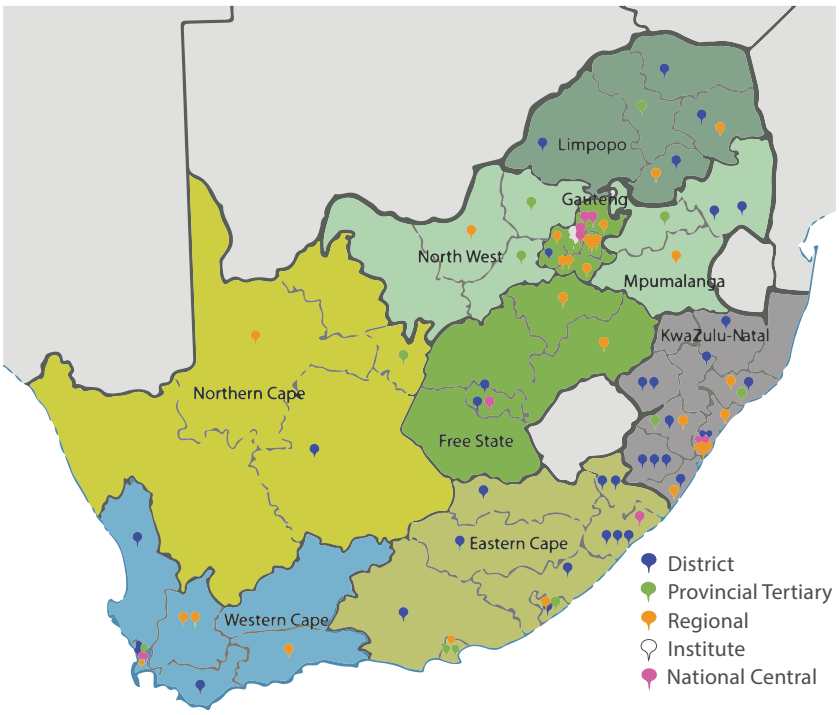


Figure 29: Accredited diagnostic laboratories in the 2020/21 financial year

Figure 30 shows that the first laboratory was accredited in the 2000/01 financial year and the majority of the laboratories (62 laboratories or 68%) had been accredited in the last four financial years. The figure also shows the accredited laboratories divided into different tiers of service provision.

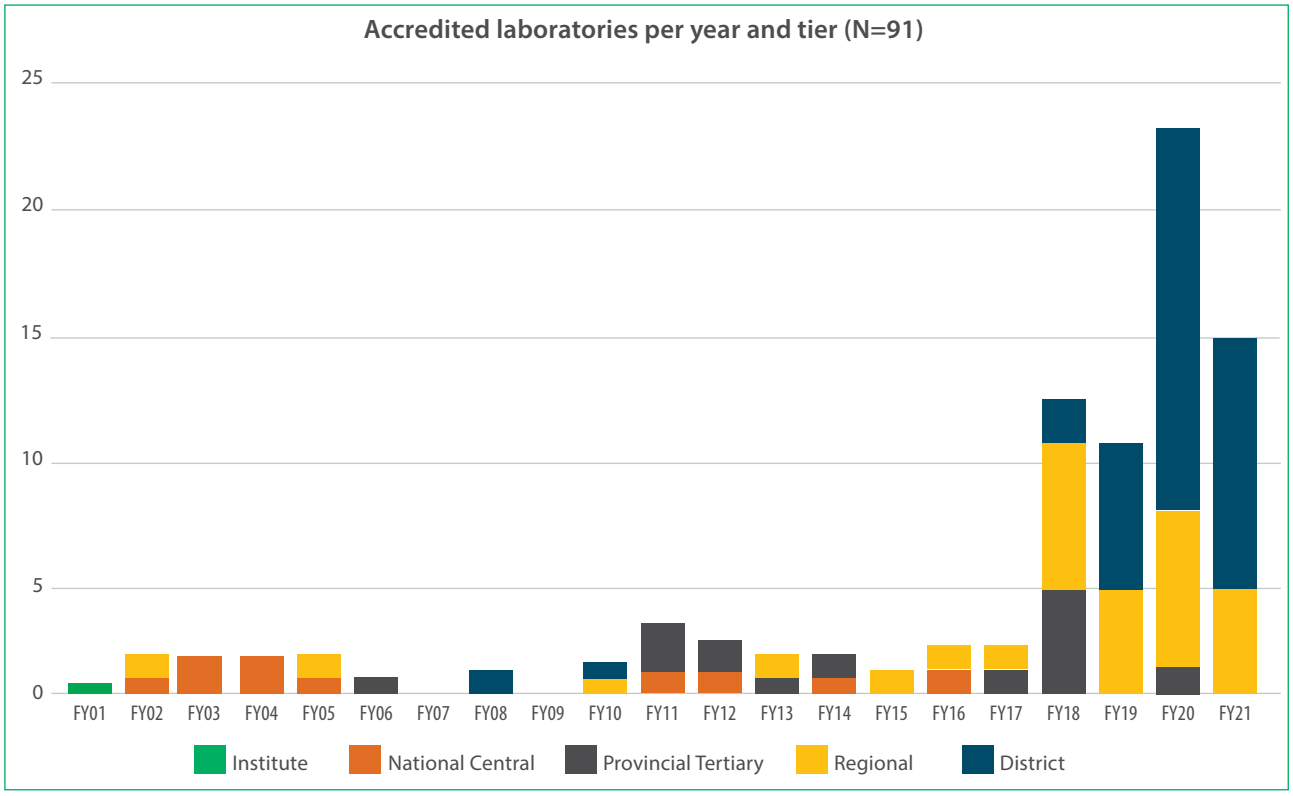


Figure 30: Accredited laboratories by tier in the 2020/21 financial year

Accreditation of occupational hygiene laboratories – ISO/IEC 17020:2012

The Occupational Hygiene section of the NIOH maintained its accreditation during the financial year.

Accreditation of public health laboratories – ISO 17025:2017

The number of accredited laboratories was maintained, and is as follows:

- National Institute for Communicable Diseases
- National Institute for Occupational Health
- Public Health in Durban

Accreditation of proficiency testing schemes – ISO/IEC 17043:2010

The number of accredited PTSs increased from 24 in the previous financial year to 26 in 2020/21. There were also two extension of scopes in the existing accredited schemes.

Newly accredited PTSs are as follows:

- Hepatitis B Surface Antigen PTS
- Malaria Rapid Diagnostic Tests PTS
- Endocrine PTS (number of accredited hormones increased to include insulin and testosterone)
- Therapeutic Drug Monitoring (TDM) PTS (number of accredited drugs increased to include lithium)

The following schemes maintained their accreditation:

- Blood gas
- Blood morphology
- Beta hCG
- Cardiac markers
- Chemistry – general
- C reactive protein
- Cryptococcus latex antigen
- Differential count – manual
- D-Dimer
- Endocrines
- Erythrocyte sedimentation rate
- Flowcytometry (including CD4)
- Full (complete) blood count
- Reticulocyte counts (manual)
- HIV serology
- HIV early infant diagnosis
- Mycology moulds
- Mycology yeast
- Non-treponemal syphilis
- Parasitology – blood
- Parasitology – stool
- TB microscopy
- Treponemal syphilis
- TDM

One application was sent to SANAS for the accreditation of the TB line probe assay PTS.

Certification of Support Services and Diagnostic Media Products – ISO 9001:2015

During the 2020/21 financial year, the number of certified diagnostic media product (DMP) departments was maintained, and is as follows:

- DMP – Greenpoint
- DMP – Sandringham
- NIOH Biobank

The QA Unit went through a successful recertification audit and was recommended to apply for external audits for certification in February 2021.

In order to continue implementation while facing COVID-19 challenges, innovative ways were introduced during the 2019/20 financial year:

- six training courses that had been developed in-house were offered through a virtual platform to 349 attendees compared to 17 who had attended external courses in the previous financial year;
- five departments managed to conduct management review meetings compared to three in the previous reporting period; and
- remote internal audits were introduced. A total of 22 out of 33 units (67%) were audited compared to nine (27%) in 2019/20 and 13 (39%) in 2018/19. Figure 31 shows the trend analysis of compliance in the past three financial years, even though the number of units audited was not the same in each financial year. The average compliance remained at over 80% in the last two financial years.

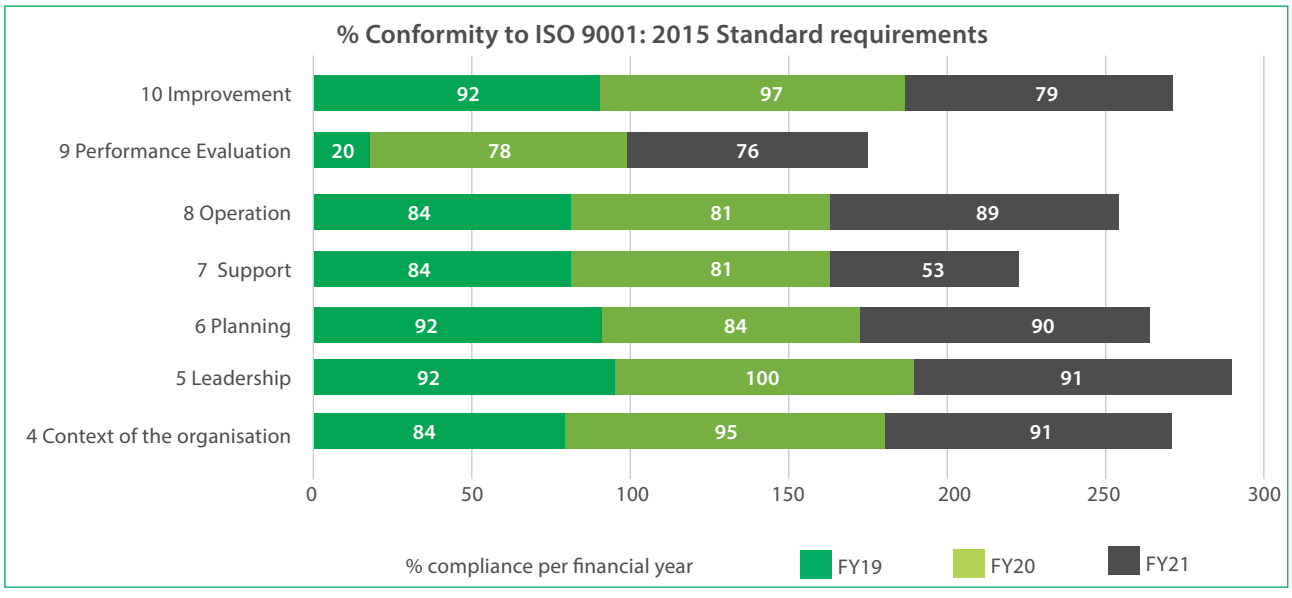


Figure 31: Percentage compliance of support service departments in all three audit cycles

Proficiency testing schemes

The QA Unit continued to measure the quality of results issued by the NHLS' laboratories through the provision of PTSs. In addition to the NHLS' laboratories, enrolment in PTSs is also offered to private laboratories in South Africa, as well as public and private laboratories in 24 other countries.

The NHLS' PTS performance has continued to be above its annual strategic target of 90% over four consecutive years, with 96% of reporting laboratories achieving average results of more than 80%, as seen in Figure 32.

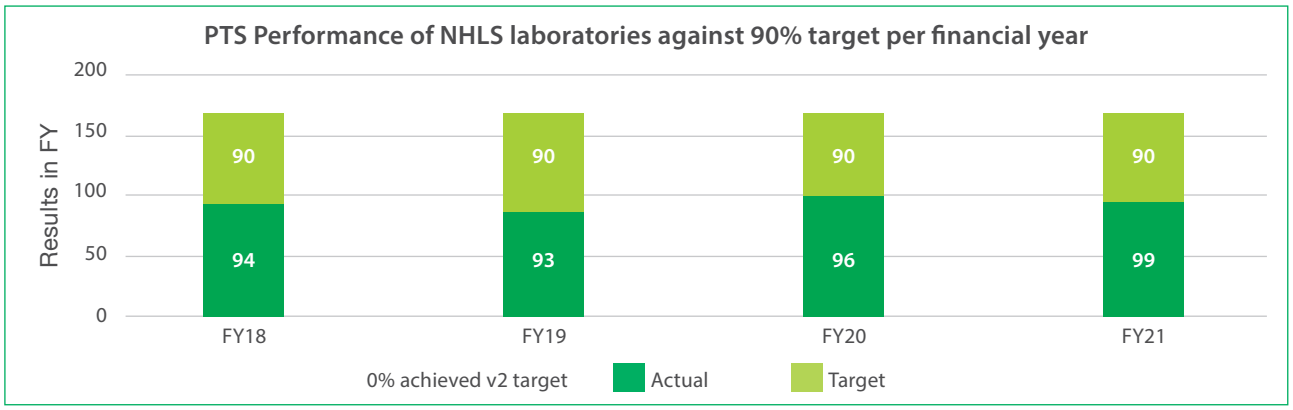


Figure 32: Average performance of NHLS laboratories on the NHLS' PTS over four years

Some of the PTS highlights for the year under review include the following:

- Three new schemes were introduced in the period under review: automated differential count, coagulation and SARS-CoV-2 molecular testing.
- The web-based software implementation started with the following achievements:
  - Two pilot studies were completed
  - Participants were trained
  - Fifteen PTS schemes were completed and went live for the final pilot before sign off
- The automated enrolment system was improved and introduced to all participants, including over 4 000 POCT facilities and clinics.

Quality compliance audits

A total of 134 non-accredited laboratories underwent internal quality audits managed by the QA Unit at least once in the period under review. Despite COVID-19-related challenges affecting laboratories, the laboratories exceeded their set target. The percentage of laboratories that achieved an average of 80% or more increased by 7% for the second consecutive year to 93%, compared to 86% in 2019/20 and 79% in 2018/19.

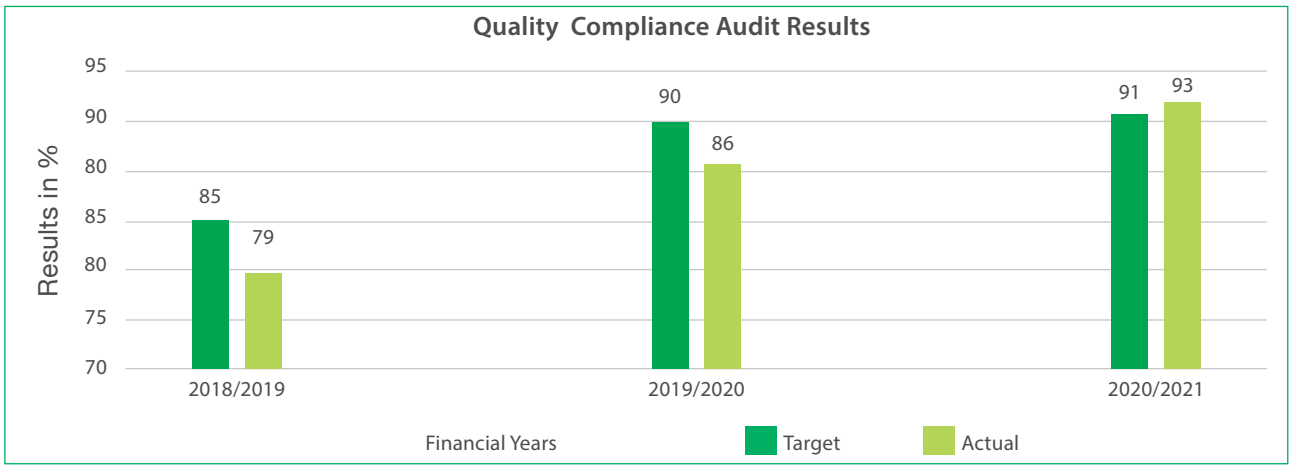


Figure 33: Quality compliance audit results over three financial years

Health Technology Assessment Unit

During the 2020/21 financial year, the role of health technology assessment (HTA) became more important for the country to deal with many devices that were introduced to address the COVID-19 pandemic. The relationship between the NHLS and SAHPRA became stronger as NHLS staff not only gave advice, but had to conduct many evaluations and process many applications received by SAHPRA to address the pandemic.

The HTA Unit received 32 applications compared to 40 in the previous financial year. The applications received were for instrument upgrades, a new instrument, a new reagent, a POCT instrument and a POCT reagent and reagent upgrades. Figure 34 shows the activities related to HTA for the last three financial years.

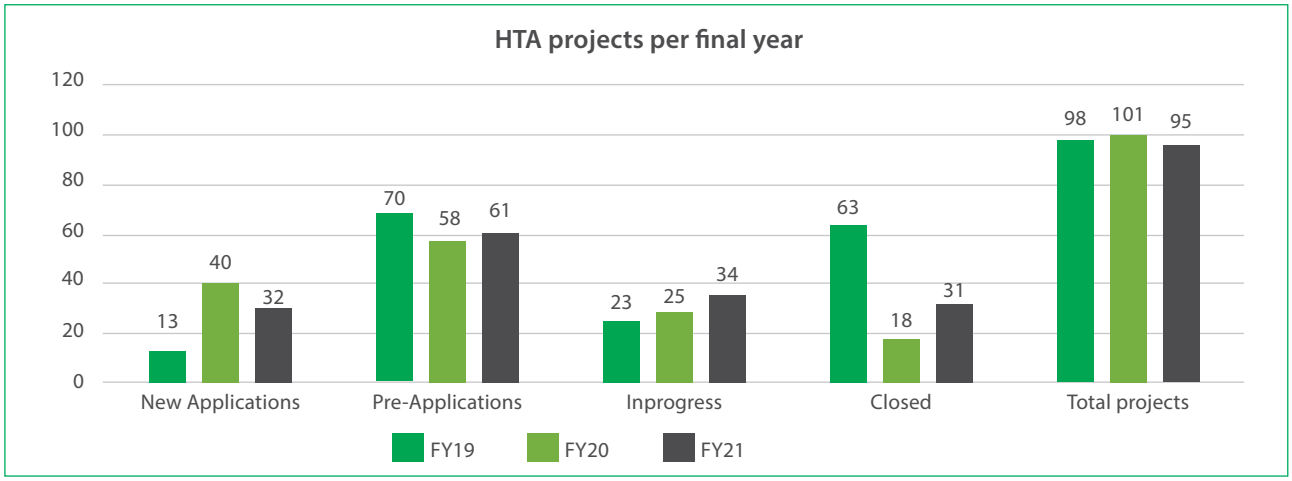


Figure 34: Summary of HTA activities over three years

Post-market Surveillance

The NHLS' Post-market Surveillance (PMS), QA Unit aims to ensure that the in-vitro devices (IVDs) produced or placed in laboratories continue to meet the same quality, safety and performance requirements as when they were initially placed in the NHLS laboratories. Resources in the QA Unit allow the NHLS to offer only reactive PMS, i.e. after an issue has occurred related to IVDs and not a proactive PMS to scan for potential issues related to IVDs.

Eleven PMS incidents were recorded for the 2020/21 financial year compared to 17 in the previous financial year and 24 in 2018/19. All PMS incidents were fully addressed and closed. The incidents were categorised into contractual and technical complaints. Of these, six records (55%) were contractual and five were technical (45%). Figure 35 shows the number and category of PMS incidents recorded per financial year over the last three years.

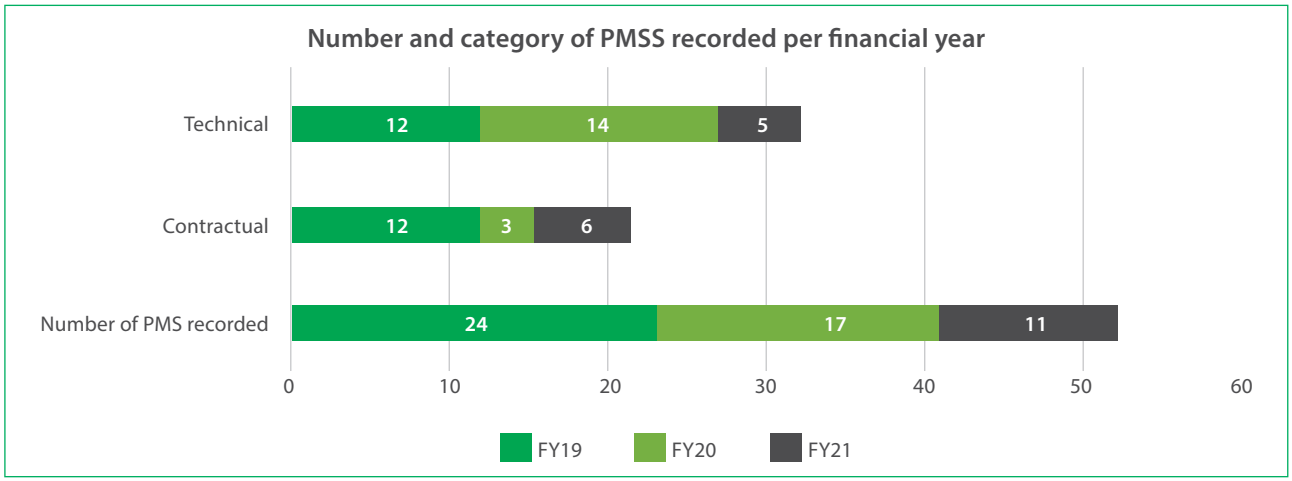


Figure 35: Classification of PMSs handled by the NHLS over three years

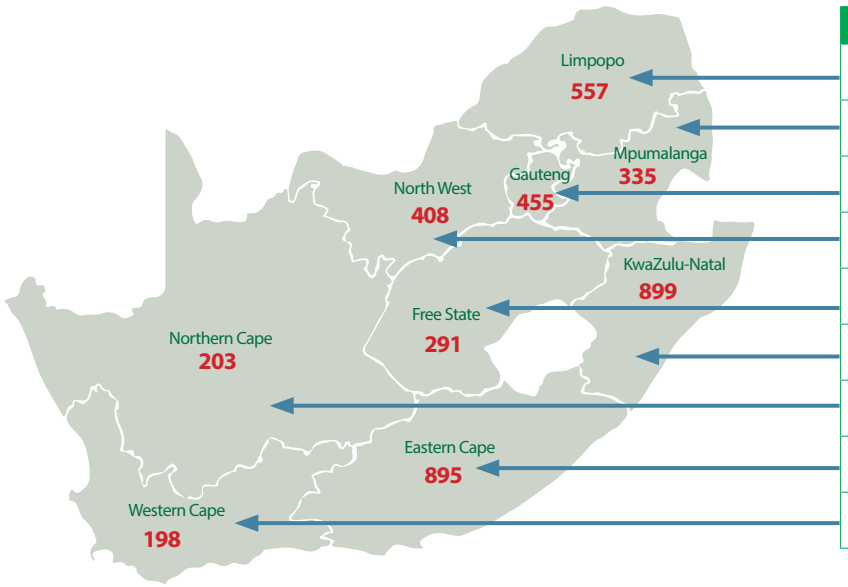
Q-Pulse QMS Software

The staff in the QA Q-Pulse Unit continued to be instrumental in the implementation of the NHLS' quality management system (QMS), as well as the maintenance of certification and accreditation. Two types of training were offered: Q Pulse Document and Corrective Action, and Preventive Action. Only five people were trained in this financial year. This was a major decline compared to 105 in the previous financial year and 226 in 2018/19. Even though more laboratories were accredited and there was a significant increase in compliance to International Organisation for Standardization (ISO) standards. The standardisation of documents continued to be a success. In the financial year under review, 1952 new documents were activated. This represents a decline of 45 documents when compared to previous financial year (from 8443 in 2019/20 to 8398 in 2020/21).

Grant projects

The Continuous Quality Improvement (CQI) project funded by the CDC continues to complement activities in the QA Department for both accreditation and certification, as well as implementing QMS at South African HIV POCT sites.

The number of POCT sites enrolled on the HIV PTS from nine provinces dropped from 4 284 in the previous financial year to 4 125 during the period under review. Some clinics were closed. The facilities have already been enrolled for both independent quality control (IQC) and PTSs. The overall performance of the healthcare facilities increased from 85% in 2019/20 to 91% in 2020/21. Figure 36 shows the number of facilities participating per province and the average performance over the past two financial years.



Province	FY20	FY21
Limpopo	79	78
Mpumalanga	96	86
Gauteng	86	90
North West	59	83
Free State	76	79
KwaZulu-Natal	93	86
Northern Cape	42	78
Eastern Cape	76	46
Western Cape	68	79

Figure 36: Performance and number of South African clinics enrolled on the NHLS PTS

2.5 Performance Information by institutes

2.5.1 National Institute for Communicable Diseases

Prof Adrian Puren
Interim Executive Director

Introduction

The COVID-19 pandemic has repositioned the strategic importance of the NICD in detecting, containing and responding to infectious disease threats in South Africa, the Southern African Development Community (SADC) region and Africa. As a credible health partner to the National Department of Health, the WHO and the Africa CDC, the institution provides technical support and expertise through the continual surveillance of communicable diseases, outbreak response, specialised diagnostic services, research and training, capacity building and provincial epidemiology services. It furthermore provides the global health community with valuable information on communicable diseases.

National Treasury funds core surveillance activities through the provision of a conditional grant, while select research projects are grant-funded from external agencies and donor funds. The NICD comprises seven disease-focused centres, including a transversal Division of Public Health Surveillance and Response (DPHSR). The 500-strong staff complement includes pathologists, scientists, epidemiologists, medical technologists and technicians, and surveillance officers.

Highlights

The transversal support services that were pivotal in supporting the NICD COVID-19 response include Information Technology, Communications, Biosafety and Biosecurity, and Occupational Health.

The Information Technology team created the platforms for the onboarding of private sector laboratory SARS-CoV-2 test data and developed the Outbreak Response System for COVID-19, while rapidly enabling electronic systems for the new way of work.

The Division of Biosafety and Biosecurity was instrumental in initiatives that included training of laboratory staff in preparation of SARS-CoV-2 virus isolation and proliferation. System upgrades, commissioning and the recertification of the Centre for Emerging Zoonotic and Parasitic Diseases (CEZPD)'s BSL4 and BSL3 facilities were completed with continued biocontainment engineering support for the NDoH.

The staff, residents and graduates of the South African Field Epidemiology Training Programme (FETP) responded to deal with acute demand for epidemiological capacity for COVID-19 and 15 other outbreaks throughout all the provinces. The FETP continued its training by developing a Google online classroom platform, an innovation mirrored by other programmes. The team developed a regional strategic plan to facilitate the training of 200 field epidemiologists in southern Africa and secured funding

from the US and Africa CDC to realise this need. The University of Pretoria awarded Master of Public Health degrees to two MSc residents and the University of the Witwatersrand awarded degrees to five FETP residents. The South African FETP offered applied epidemiology training to 35 district and provincial frontline health professionals in the Eastern Cape, while data management training was provided to 115 staff in seven districts in the Northern Cape and the Free State.

The Occupational Health Clinic attended to 1 070 visits throughout the year. Some 741 employees from both the NHLS and the NICD were tested for COVID-19, with 132 testing positive. In addition, risk assessments, counselling and occupational health support was provided to those who have been exposed to COVID-19.

The Communications Unit was a hive of activity, delivering impressive results. Media coverage increased by 38%, social media platforms grew by 9% on Twitter, 51% on Facebook and 558% on LinkedIn, while 47 videos were produced.

The Centre for Emerging and Parasitic Diseases

The Centre for Emerging and Parasitic Diseases (CEZPD) continued to support the malaria control and elimination agenda of the provincial, national and regional programmes. In collaboration with the University of California-San Francisco, it is establishing a targeted amplicon-sequencing platform to advance malaria elimination by providing more accurate information on parasite relatedness and movement in South Africa.

In response to the potential threat that malaria parasites with deletions in the HRP2 gene pose to the effectiveness of HRP2-based malaria rapid diagnostic tests, the CEZPD implemented a surveillance programme for the detection of parasites carrying these deletions. The morphological keys to the Anopheles mosquitoes of sub-Saharan Africa were revised and updated from the 1987 version, providing an important resource for general vector biology and control. To support malaria elimination in South Africa and the greater southern African region, the CEZPD established a regional malaria slide bank. To date, 154 batches, comprising 26 623 slides, six proficiency testing surveys, as well as microscopy training slide sets, have been produced and shared with other southern African countries.

As a part of a bio-surveillance programme for arboviruses, the CEZPD investigated the possibility of undetected Rift Valley Fever Virus (RVFV) infections in patients visiting healthcare facilities in the northern parts of KwaZulu-Natal between April 2018 and August 2019. The detection of IgM and IgG antibodies to RVFV in human serum samples confirms the recent circulation of the virus in the tropical coastal plain region of South Africa in the absence of reported clinical disease and indicates that RVFV infections are misdiagnosed or underreported. This situation highlights an urgent need for the improvement of diagnosis and awareness of RVFV and other arbovirus diseases in this part of South Africa in order to reduce the disease burden and the potential misuse of anti-malaria treatment.

Centre for Enteric Diseases

The Centre for Enteric Diseases (CED) provides the South African community with epidemiological and laboratory support in response to food- and water-borne outbreaks. During the 2020/21 financial year, the centre provided epidemiological and laboratory testing support for 18 outbreaks, and documented a further 45 outbreaks in which further investigation was hampered by either insufficient epidemiological or sample testing data.

In outbreaks associated with bacterial pathogens, whole-genome sequencing (WGS) of isolates was conducted to assist with investigations and outbreak source attribution.

All listeria cases reported to the Notifiable Medical Conditions (NMC) system were actively followed up, and the WGS of isolates was performed to ensure the early detection of any potential clusters or outbreaks.

Typhoid fever surveillance was enhanced through the routine WGS of typhoid fever isolates, which assisted in the investigation of an ongoing outbreak and monitoring of antimicrobial resistance trends.

Routine diarrhoeal disease sentinel surveillance in selected sites continued, with plans to expand surveillance to additional sites that had been temporarily halted because of the COVID-19 pandemic. A remarkable decline in the prevalence of rotavirus was noted in 2020, coupled with the absence of a seasonal increase in cases typical of the annual rotavirus season. ***Shigella*** spp. continued to be the leading cause of diarrhoeal hospitalisations in children under five years of age.

Other areas of research in the centre include increasing the capacity for the WGS of enteric bacteria to improve outbreak detection and investigation, improved diagnosis of common enteric infections in Africa, and the use of metagenomics on sewage samples to explore antimicrobial resistance.

Centre for Healthcare-associated Infections, Antimicrobial Resistance and Mycoses

The Centre for Healthcare-Associated Infections, Antimicrobial Resistance and Mycoses (CHARM), incorporates two national reference laboratories for antimicrobial resistance (AMR) and mycoses, and houses the National Biological Sample Collection of pathogenic bacteria and fungi. The centre serves as a WHO collaborating centre for AMR. It is the national focal point for the WHO's Global Antimicrobial Resistance Surveillance System (GLASS) and supports national and regional PTSs. In 2020/21, the centre collated electronic laboratory data on AMR pathogens causing bloodstream infections from the public and private sector, and reported this data through an AMR dashboard.

The centre completed surveillance of ***Acinetobacter baumannii*** bacteraemia, continued surveillance for carbapenem-resistant ***Enterobacterales bacteraemia***, ***Candida auris*** infections and cryptococcal meningitis, and started new surveillance for Enterococcus bacteraemia. In addition, the centre supported data collection for sites participating in the national DoH/Clinton Health Access Initiative (CHAI)/Unitaid flucytosine access programme for cryptococcal meningitis. The centre set up national surveillance for neonatal infections (Baby GERMS) and completed retrospective data collection for six years (2014 to 2019) and the enrolment of neonates into an enhanced surveillance project at six regional hospitals' neonatal units. Work continued on a multi-year laboratory project to support and improve the national NHLS CrAg screening programme through laboratory training, a PTS, results for action, sample re-testing and new assay evaluations.

The mycology team continued to evaluate the effectiveness of this CrAg screening programme using a retrospective cohort study design. The mycology reference laboratory completed work on a case series describing blastomycosis in South Africa, including a newly discovered human pathogen called ***Blastomyces emzantsi***.

Centre for HIV and STIs

The Centre for HIV and STIs (CHIVSTI) has a strong track record in the research disciplines of HIV virology, HIV immunology, HIV/STI epidemiology, HIV/STI diagnostics and HIV-STI interactions. It addresses the challenges of HIV and STI diseases through various programmes, including but not limited to surveillance of disease burden and antimicrobial resistance, the measurement of endpoint infections and detection, broadly neutralising antibodies as part of prophylactic HIV vaccine and antibody-mediated protection clinical trials and exploring an HIV "cure" strategy.

SARS-CoV-2 has been a significant focus of the HIV Virology Section in the past year. The Centre responded to the COVID-19 outbreak by seconding staff to the Emergency Operations Centre from March 2020. Several existing assays were adapted for COVID-19 research, including serological assays using spike and receptor domain ELISAs, neutralisation assays and Fc effector assays. These assays supported an array of projects, including the investigation of convalescent plasma for the treatment of severe disease and the measurement of immune correlates in SARS-CoV-2 infected longitudinal cohorts and vaccine trials, including the South African Ox1Cov-19 Vaccine VIDA-Trial trial.

During the period under review, the Centre continued to implement enhanced congenital syphilis surveillance with support from the WHO. The enhanced surveillance involved the introduction of a case investigation form (CIF) to accompany the standard NMC case notification form (CNF). The NICD, in collaboration with the national DOH and its partners, has scaled

up training of the congenital syphilis notification process to raise awareness of the condition and improve the quality of surveillance data. It is expected that the Centre's congenital surveillance will provide data for evaluating the impact of the dual HIV/syphilis to be introduced in the 2021/22 fiscal year.

Centre for Respiratory Diseases and Meningitis

During the period under review, the Centre for Respiratory Diseases and Meningitis (CRDM) continued to play a leading role in the response to the COVID-19 pandemic in South Africa. It supported the National COVID-19 Incident Management Team, playing a leading role in the epidemiology and laboratory streams. The centre produced regular COVID-19 surveillance reports, including, but not limited to the Weekly Epidemiological Brief, the Weekly Testing Summary and the COVID-19 reproductive number.

A number of detailed epidemiologic reports were also published in the ***Communicable Diseases Surveillance Bulletin***. The CRDM laboratory set up a SARS-CoV-2 diagnostic polymerase chain reaction (PCR) test to detect the first cases of COVID-19 in the country, and then supported roll-out to public and private-sector laboratories throughout the country, as well as supporting African laboratories as needed.

The CRDM laboratory is a WHO COVID-19 regional reference laboratory and has provided support to many African countries in this capacity. Initially, this was done through testing, training and support to establish in-country testing, coupled with ongoing support for quality assurance and interlaboratory comparisons. More recently, this has expanded to include assisting with the sequencing of SARS-CoV-2-positive specimens and supporting in-country sequencing efforts.

The CRDM performed systematic sero-surveys of SARS-CoV-2 antibodies in three provinces and implemented studies of COVID-19 shedding and disease progression, burden and household transmission and molecular epidemiology.

The Centre continued with the core function of surveillance. Syndromic surveillance programmes included the pneumonia and influenza-like illness surveillance systems in public hospitals and health clinics, as well as the private general practitioner network (Viral Watch). These programmes aim to describe the burden, seasonality and characteristics of influenza, respiratory syncytial virus (RSV) and ***Bordetella pertussis,*** and were expanded to include systematic surveillance for COVID-19. Laboratory-based surveillance programmes including pneumococcus, meningococcus, ***Haemophilus influenzae***, and Group A and Group B streptococcus with a focus on outbreak detection and the impact of interventions. These programmes documented marked reductions in the burden of all other respiratory pathogens under surveillance in 2020.

In 2020, four additional postgraduate students joined the CRDM as part of the NIH-funded South Africa-Pittsburgh Public Health Genomic Epidemiology Research Training Programme (SAPPHGenE), which aims to develop research in public health genomics in South Africa.

Centre for Tuberculosis

The year under review was largely focused on the COVID-19 response, with senior staff providing critical support to the COVID-19 pandemic response. Prof Nazir Ismail served as the NICD lead on the Incident Management Team, Dr Harry Moultrie served on the COVID-19 Ministerial Advisory Committee and coordinated the South African COVID-19 Modelling Consortium (SACMC), which provided modelling support for multiple structures, including the national DoH, the National COVID-19 Command Council (NCCC), the MAC, National Treasury and the public.

The impact of the COVID-19 epidemic and public health restrictions on laboratory investigations and the diagnosis of TB in South Africa was therefore investigated. The centre provided the National TB Programme and National TB Think Tank with a bi-weekly analysis of Xpert TB testing volumes, Xpert positive tests, positivity rate and rifampicin-resistant tests to support the TB COVID-19 recovery plan.

As part of the advancing diagnostics, epidemiology and treatment function of the centre, several new cutting-edge diagnostic technologies were evaluated during this period, which include the Xpert MTB/XDR, GeneXpert OMNI, Hain Fluorotype and BDMAX platforms for the rapid molecular detection of ***M. tuberculosis*** and accompanying drug resistance. Data generated was submitted to the WHO for review and was used for the recent recommendations of these molecular assays. The centre also initiated assessments of next-generation sequencing technologies (whole-genome sequencing) for diagnostic utility in predicting drug resistance and the molecular epidemiological surveillance of transmission networks and an early warning system for outbreak detection in two high-burden districts in South Africa.

The Comprehensive Resistance Prediction for Tuberculosis, an international consortium of which the centre is a full member, established to delineate genetic drug resistance prediction using WGS, has completed its five-year programme. Preliminary data generated from this activity has been shared with the WHO to develop the first mutation catalogue associating mutations across the genome with drug resistance. The WHO has also appointed the centre to Technical Expert Groups for the development of and guidance on policies and recommendations related to these new technologies.

Centre for Vaccines and Immunology

As the regional reference laboratory for polio surveillance, the Centre for Vaccines and Immunology (CVI) identified Vaccine-derived Polio Virus Type 1 (VDPV1) from Madagascar, and VDPV2 from Angola, Burkina Faso, Congo, Cote d'Ivoire, the Democratic Republic of Congo, Ethiopia, Guinea, Liberia, Mali, Niger, the Republic of South Sudan and Sierra Leone from acute flaccid paralysis cases. Type 2 Sabin polio viruses were detected from countries using monovalent oral polio vaccine Type 2 to halt VDPV2 transmission in Angola, Burkina Faso, Cote d'Ivoire, the Democratic Republic of Congo, Ethiopia, Guinea, Mali, Niger, the Republic of South Sudan, Sierra Leone and Zambia. From environmental sewage samples, VDPV2 was confirmed from Angola, Congo, Cote d'Ivoire, the Democratic Republic of Congo, Ethiopia, Liberia, Niger and the Republic of South Sudan. Sabin Polio Virus Type 2 was confirmed in environmental samples from Angola, Burkina Faso, Cote d'Ivoire, the Democratic Republic of Congo, Ethiopia, Niger, the Republic of South Sudan and Zambia. From South African environmental surveillance, the sequencing of a Sabin Polio Virus Type 3 suggested that polio vaccine coverage in the district and/or province may be suboptimal and heightened surveillance was recommended. The NICD is one of few sites globally who plan to host a Polio Essential Facility for work with polio viruses under high containment.

Building on its expertise in environmental surveillance from sewage, the centre is leading the South African Collaborative COVID-19 Environmental Surveillance (SACCESS) network to identify and map SARS-CoV-2 distribution in sewage. From 1 April 2020 to 31 March 2021, 205 wastewater samples were processed for SARS-CoV-2 from nine sites in Gauteng, two sites in the Western Cape, two sites in the Free State, four sites in the Eastern Cape, two sites in KwaZulu-Natal and one site in Limpopo. SARS-CoV-2 was identified in 169 samples (82%). Using next-generation sequencing, the 501Y.V2 variant was successfully detected in a sewage sample from the Eastern Cape in November 2020. SARS-CoV-2 is considered non-infectious from sewage samples, but the viral RNA remains detectable. Sewage monitoring may provide accessory information to the national DoH for planning geographically localised interventions. Sewage surveillance infrastructure holds promise for monitoring other pathogens.

Division of Public Health Surveillance and Response

The Division of Public Health Surveillance and Response (DPHSR) played a pivotal role in the national COVID-19 pandemic response through the activities of the Emergency Operations Centre, the Outbreak Response Unit and the Provincial Epidemiology Team. This included daily epidemiological updates to the NDoH at a national and provincial level and an interactive dashboard to assist provinces in their response. The DATCOV hospital surveillance platform provided valuable data on COVID-19-related hospitalisations and deaths, the long-term effects of COVID-19 and the impact of co-morbidities on COVID-19 mortality.

The Division participated in the National Incident Management Team, providing epidemiological expertise and guidance. Support was provided to the pathogen-specific centres within the NICD, and to the DoH for other infectious disease outbreaks. The NICD clinicians' call service provided valuable support to clinicians facing challenging infectious disease case diagnosis and management.

The provincial Epidemiology team provided operational support to the provinces, including outbreak and surveillance activities, data analysis and daily situation reports. The provincial epidemiologists provided an important link between the NICD and the provincial health departments in responding to COVID-19, as well as to HIV and TB.

The GERMS-SA surveillance platform supported surveillance within the pathogen-specific NICD centres. These nationwide activities covered a broad range of pathogens and included laboratory surveillance, syndromic surveillance for pneumonia and influenza-like illness, acute febrile illness, neonatal sepsis and diarrhoea at sentinel hospitals and clinic sites. The platform was also used for COVID-19 specific studies.

The NMC Surveillance System fulfilled its mandate to receive notifications on diseases and conditions of public health importance. COVID-19 was included in the list of notifiable diseases, and additional modules are being added, including the long-term sequelae of COVID-19 infection. The NMC Surveillance System is in the process of being migrated to a new platform that will optimise and enhance use by its many stakeholders.

National Cancer Registry

The National Cancer Registry is the main source of cancer incidence data for the country used for cancer resource allocation and programme implementation. It provides both pathology- and population-based cancer registration data for South Africa through its varied cancer surveillance programmes. During the period under review, the NCR produced the 2016 and 2017 cancer incidence reports for South Africa, highlighting the leading cancers in the country, but also demonstrating age standardised, age-specific incidence rates and lifetime risks for all cancer types. The pattern of cancers reported was consistent with previous years, with breast and cervical cancer being the most common cancers in women, and prostate and colorectal cancers being the leading cancers in men.

The NCR also published the 2019 population-based cancer registry results from the Ekurhuleni District of Gauteng. With hospital wards being closed, outpatient services being suspended and restrictions on surveillance officer movement due to COVID-19, overall case finding was limited. Despite these challenges, 2 541 new cancer cases were registered for the year under surveillance. The NCR will continue to monitor the incidence of cancer cases reported from the Ekurhuleni District to provide a comprehensive picture of cancer incidence in the country.

An exciting new initiative at the NCR is the establishment of a Childhood Cancer Registry for the country. Childhood cancers are classified and reported in a unique manner that is different to adult cancers. Therefore, the registration of childhood cancers requires a dedicated and uniquely skilled expert. The NCR is pleased to announce that Natasha Abraham was nominated and appointed as the regional expert for childhood cancers by the International Agency for Research on Cancer (IARC) Global Initiative for Cancer Registry Development. The NCR plans to publish its first Childhood Cancer Incidence Report in the new financial year.

Appreciation

The NICD would like to thank the NHLS for its innovative leadership and key laboratory support during the COVID-19 pandemic. It also acknowledges the technical and financial support from the national DoH, National Treasury, as well as development and technical partners. The Institute remains resolute and unswerving in its efforts to manage communicable diseases and inform public health policies. It believes that improving regional and global collaborative efforts will contribute to the betterment of all and that its successes will ultimately benefit society as a whole.

2.5.2 National Institute for Occupational Health

Dr Spo Kgalamono
Executive Director

Introduction

The National Institute for Occupational Health plays an important role in supporting government's occupational health efforts. It is recognised as a Centre of Excellence for occupational health and functions as a national and regional source of knowledge and expertise to the South African government, industry and labour, the SADC countries and the African region. It provides advice and assistance, conducts research and develops capacity through teaching and training for the purpose of promoting healthy conditions in workplaces and improving the health of workers.

Under the leadership of the NHLS, the NIOH had numerous highlights in the area of occupational health and safety during the period under review. The Institute's multidisciplinary teams participated in a significant number of OHS engagements in both the public and private sectors, ranging from partaking in cutting-edge research at a national and global level to supporting innovative programmes to assist vulnerable workers. In the process, the NIOH collaborated with a significant number of key workplace role players locally, nationally and internationally. This, in turn, contributed to the Institute gaining a new body of knowledge that will enhance and supplement its future efforts to help ensure good occupational health and safety in all workplaces.

The NIOH implemented several targeted programmes and training initiatives for its key partners, local societies and stakeholders during the period under review. These included collaborations and partnerships with the following:

- National and Provincial Departments of Health;
- Department of Employment and Labour and the Department of Mineral Resources and Energy (DMRE);
- South African Society of Occupational Medicine;
- African Regional Association of Occupational Health;
- South African Society of Occupational Health Nursing Practitioners;
- Southern African Institute for Occupational Hygiene (SAIOH);
- Mine Medical Professionals Association (MMPA); and
- African Union Development Agency-New Partnership for Africa's Development.

Highlights

The NIOH played a significant role in some notable developments in occupational health and safety in South Africa. A number of staff members represented the NIOH at key high-level decision-making technical committees, including the National Economic Development and Labour Council, the national DoH and the Department of Employment and Labour. This entailed

drafting and revising specific occupational health legislation and guidelines in both the formal and informal economy. In the last quarter of the period under review, organised labour and the national DoH commissioned the NIOH to conduct a nationwide evaluation of occupational health services, focusing on the functioning of OHS committees in the health sector to ensure that OHS services in the sector are in line with the DEL's direction on COVID-19.

The Occupational Health and Safety Information System (OHASIS) supports surveillance, compliance with occupational and environmental health and safety (OEHS) legislation and provides information for research. During the period under review, the OHASIS has been extensively adapted to cater for new challenges posed by COVID-19, and further enhancements were made to cater for the unique needs posed by the NHLS' laboratory environment.

The NIOH's specialised laboratories continue to maintain quality management system accreditation year on year. The Institute is the only entity in South Africa that has obtained accreditation on four different quality management systems: ISO 15189 (medical laboratories), ISO 17025 (testing and calibration laboratories), ISO 17020 (conformity assessment for inspection bodies) and ISO 9001. It has also been able to provide pre-SANAS internal audits, training and support to NHLS laboratories, including proficiency testing scheme guidance to staff.

The Institute's newsletter, NIOH *OccuZone,* continued to be used as a medium to share information on the Institute's activities. This publication, which is disseminated quarterly, details current research underway, specialised service delivery and the Institute's teaching and training activities. In addition, the NIOH has increased its digital footprint through the effective utilisation of the social media platforms Twitter and YouTube. These communication channels provided the opportunity to network on a global scale. They assisted the Institute to target specific stakeholders through tailored communication and provided a diverse public relations platform to share information.

COVID-19 activities

The year 2020 was dominated by the COVID-19 pandemic, which impacted workplaces across the globe. While the arrival of the pandemic crippled some of the services provided by the NIOH, it provided numerous opportunities that emphasised the value of the Institute well beyond the occupational health space. As employers were legally obligated to conduct COVID-19 risk assessments, the NIOH played a significant role in designing tools to assist workplaces to conduct these assessments and adapted some tools for specific sectors and unique workplaces. These workplace risk assessments highlighted the importance of psychosocial and ergonomic hazards. The majority of stakeholders were capacitated to identify risks and implement requisite control measures to prevent and curb the spread of COVID-19 in workplaces.

The NIOH also responded to the pandemic by establishing a dedicated workplace advisory hotline, specifically for occupational health professionals, employees and employers. The hotline has been expanded to address general workplace queries beyond COVID-19. Queries from the hotline were used to form the basis for some of the webinars that catered for various occupational groups across different sectors. Webinars and other training events were used to equip industry with the tools required to protect and promote workers' health and safety, including the safe return to work during the pandemic.

To date, 57 webinars have been conducted, with over 40 000 participants being trained on COVID-19-related topics. Several posters and fact sheets were also developed and translated into local languages. In collaboration with academia and experts from the national DoH, the NIOH contributed to COVID-19 regulations, directions and guidelines related to workers and workplaces. All these materials are accessible via the NIOH's zero-rated website. Towards the end of the financial year, the Quality Council for Trades and Occupations (QCTO) accredited the NIOH as a skills development provider to offer two qualifications/programmes on Workplace Preparedness and Risk Control for a period of five years commencing March 2021.

Although COVID-19 affected many organisations negatively, the NIOH was able to repurpose its staff members to respond to the need to empower workplaces and, in so doing, raised the NIOH's profile as an occupational health knowledge hub for employers, employees and professionals within and outside South Africa.

Research

A fundamental task of national institutes for occupational health is to produce new knowledge in an effort to prevent ill health and injury, and to promote good health. The Institute has a large and varied interdisciplinary research programme that covers many issues that are important to the improvement of workers' health and the health communities living around workplaces. The topics of the scientific articles published over the year reveal the large variety of research needs in occupational health and safety in the country.

Research remained a priority for the Institute and focused on the prevention of workplace exposure, with specific reference to hazardous biological agents. In total, the few researchers at the NIOH managed to publish 43 articles in peer-reviewed journals, an increase on the previous year.

Surveillance

Surveillance of occupational health, morbidity, injury and mortality is inadequate in South Africa. Contributing to improved surveillance is a long-standing but increasingly important part of the work of the NIOH. Surveillance for occupational diseases was prioritised as a new strategic thrust during the period under review. Concerted efforts are being made to also increase the publication of surveillance reports.

A national occupational health surveillance system (OHSS) was established in October 2020 to cater for the submission of workplace COVID-19 infections, in line with government regulations and directives legislating the collection of data on COVID-19-positive employees. The OHSS provides an overview of the COVID-19 infection spectrum in the South African workforce with early identification of industries and occupational groups at high risk of infection so as to inform appropriate interventions (e.g. policy, programmatic, resources). Surveillance for all occupational diseases and injuries will be based on this system.

In addition, several other surveillance initiatives continue within the Institute. As per statutory obligation, the Pathology Disease Surveillance (PATHAUT) report was completed and is accessible on the NIOH website. The Institute also provided COVID-19 Weekly Sentinel Hospital Admissions Surveillance for Healthcare Workers.

International Liaison

The NIOH maintained its WHO Collaborating Centre status. This is an affirmation and recognition of the Institute's achievements in supporting the WHO's occupational health programmes, and the continuation of opportunities for partnerships and projects with the network of collaborating centres around the world. The NIOH played a prominent role in the WHO's programme on vulnerable workers, such as those in the informal economy.

The NIOH fostered strong international relationships through dedicated collaboration and networking efforts with key international agencies, such as the WHO, the International Labour Organisation (ILO), AUDA-NEPAD, the International Commission on Occupational Health (ICOH), the National Institute for Occupational Safety and Health of the Centres for Disease Control and Prevention (NIOSH-CDC), USA, the Finnish Institute for Occupational Health (FIOH), the Health and Safety Laboratory (HSL) of the UK, Workplace Health Without Borders (WHWB) and the Organisation for Economic Cooperation and Development (OECD).

Moving to the new financial year - COVID-19 and a changing world of work

It is expected that COVID-19 and the consequent changing world of work will preoccupy much of the Institute's planning, reorganisation and work for the near future. Many technical questions on protecting employees and employers from occupational hazards and their consequences need to be answered. The research projects listed in the body of this review are illustrative of them. All of working life may be altered to some extent: the way we work at home, in the informal economy,

at businesses of all sizes, factories and mines will change in unpredictable ways, and the work-related health effects that accompany these changes – some bad and some good – will need to be assessed and managed. South Africa is, unfortunately, all too familiar with unemployment and under-employment. The expected increase in unemployment will have many negative consequences for workers. Although new to the NIOH, the Institute may need to consider aspects of unemployment and worker health, in collaboration with other partners. The informal economy, which is large already, will probably expand rapidly, and NIOH programmes in this economic sector will need to be geared to respond to the growing needs.

Appreciation

I wish to thank the NHLS and the NIOH management team for the strategic leadership that enabled the NIOH to deliver excellent results under resource-constrained circumstances. Staff at the NIOH continue to strive for excellence in their work. I appreciate their contribution and thank them for their hard work towards ensuring healthy, safe and ultimately sustainable workplaces. Our partners, collaborators and stakeholders are acknowledged for contributing to the successes of the NIOH during the period under review.

2.6 Support Services performance

2.6.1 Information and Communication Technology

Sibongiseni Hlongwane
Chief Information Officer

The Information and Communication Technology (ICT) department continues its aim of becoming a strategic enabler to the business operations of the NHLS. To achieve this, a number of projects were initiated to ensure that the organisation eventually transforms into a digital business. This includes Microsoft 365 deployment. This project implements strategic actions and key priorities of the NHLS' IT Department, as contained in its IT Strategy. These priorities and strategic actions include the adoption of cloud computing technologies to improve quality of service, the utilisation of digital technology to increase efficiency and productivity, and the implementation of cybersecurity to protect the NHLS' information systems and data assets. The implementation of this project will also improve collaboration between the NHLS' employees and stakeholders, such as the DoH, through the deployment of tools such as Microsoft Teams, OneDrive, SharePoint Online and Exchange Online to improve the availability of the critical email service.

In the 2019/20 financial year, the project of refreshing the ERP system infrastructure was implemented as a first phase, which included the reimaging of the infrastructure and the upgrading of the database to improve the application performance. In the 2020/21 financial year, the second phase of the project was successfully implemented, where the Oracle e-business suite was upgraded to the latest version in alignment with global standard business processes in order to improve the NHLS business processes.

The network infrastructure and data storage capacity remain at the top of the list of IT priorities to address the NHLS' business challenges. To this end, the LAN Refresh Project Phase 2 was initiated in the 2020/21 financial year. The aim of this project is to address the ailing infrastructure risk highlighted in the IT Strategy. This is in direct support of the NHLS' strategic objective for modernised and efficient IT systems. The project aims to refresh networking equipment in both data centres, the Edge network in all offices and laboratories, and to establish a corporate wireless network with guest access. A project to replace the current servers and storage was also initiated. This will result in the NHLS' current data centre solution being replaced and redesigned with a well-researched solution. The aim is to complete these two infrastructure projects in the third quarter of the 2021/22 financial year.

Information and Knowledge Management

The Information and Knowledge Management (IKM) Unit continues to provide enterprise content management (ECM) solutions as part of the digital business transformation journey by rolling out and maintaining digitalisation solutions. The ECM asynchronous scanning solution, integrated with TrakCare, contributes by making laboratory request forms available and

accessible electronically in NHLS laboratories across the country, resulting in improved auditing processes, the resolution of billing disputes and the continuous payment of invoices to the NHLS. The supply chain management solution for the scanning of tenders and requests for quotations (RFQs) contributes by making tenders, contracts and RFQs available electronically in a central repository for easier access.

Among the projects initiated in this unit are document management for team collaboration, the creation of enterprise workspaces for departments to store documents in a central repository, an extended workflow solution for business process automation, and enabled e-signatures as part of workflow approvals.

Laboratory Information System

A patient communication system was developed to allow for the sending of SMSs to patients. Patients who have been tested for COVID-19 rely on feedback from healthcare workers to know their results. To reduce the pressure on healthcare workers, patients are informed of their results by SMS.

As new instruments and tests were implemented in the laboratories, the Laboratory Information System Unit developed, tested and implemented interfaces to allow for the rapid uploading of results onto the TrakCare laboratory system. To assist with surge testing, interfaces to a number of public and private partner laboratories were implemented in rapid succession. This allows for the digital exchange of laboratory orders and results, and improved turnaround times.

The TrakCare laboratory system was implemented in the many mobile laboratories deployed during the COVID-19 pandemic. Full registration capability and results lookup were available in the mobile laboratories, and GeneXpert analysers were interfaced to allow samples to be tested directly in the mobile laboratories. With the advent of COVID-19 rapid antibody and antigen testing, the LIS Unit implemented a COVID-19 Rapid Test Reporting portal. All rapid COVID-19 tests performed in the field can be captured on the portal via mobile phones, laptops or tablets.

Corporate Data Warehousing

The Corporate Data Warehousing Unit managed to develop six dashboards. The dashboards were developed in response to the business requirement to monitor the NHLS' response to COVID-19. A Pre ISO 9001:2015 quality audit was performed. Systems availability for Informatica (extract, transform and load) and Netezza (data warehouse) was above 98%. It managed to deliver on all data requests: microstrategy reports and dashboard distributions, scheduled data extracts and interface deliveries, legal data requests, research data requests, DoH operational reports and internal NHLS operational reports.

All Netezza hardware maintenance is up to date in both production and disaster recovery environments. The unit improved the dimensions in the data warehouse to make sure that all outdated dimensions are properly updated. Appropriate processes were put in place to review them. To reduce data integrity issues, a reconciliation process was implemented to identify all records that are failing to reach the environment and a process was established to deal with the problem by including transactional system service providers.

Old and unsupported hardware was successfully decommissioned, including the old Netezza server and old Oracle data warehouse server. The Netezza and Informatica firmware were upgraded to production and disaster recovery environments. An overall security review was performed to clean up all legacy administrative user account issues. Interfaces and scheduled extracts were also cleaned up and rules were developed to review data extracted, as well as the creation of a data request renewal process, e.g. for annual renewals.

Enterprise Resource Planning

The unit successfully completed the Oracle application upgrade. This upgrade was necessary for continued support from Oracle as the older version was no longer supported. The upgrade resulted in system improvements in the form of the application of recent security patches, which improved the database security and provided for seamless future upgrades and database protection.

IT Operations

A network infrastructure tender was awarded to upgrade the NHLS' network switches and firewall security devices. The project was launched in January 2020 and will be completed in the 2021/22 financial year.

Information security programs were put in place where vulnerability assessments for the CDW, Oracle and ECM environments were conducted. A user awareness campaign was deployed to address information security issues. A portal dedicated to disseminating information regarding security was also deployed on the NHLS' intranet.

Video conferencing solutions were deployed to enable remote working and the attendance of meetings in response to COVID-19 challenges. Mobility was also enabled for many of the NHLS' IT users through the expansion and provisioning of a secure virtual private network (VPN) service. Call centres were set up for the general public with a toll-free number for COVID-19 matters.

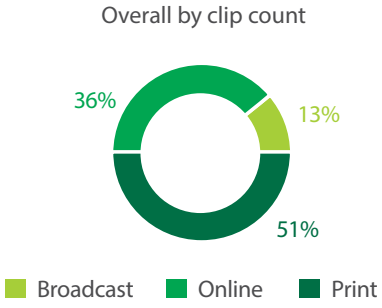
2.6.2 Communication, Marketing and Public Relations

Mzimasi Gcukumana
Senior Communication Manager

The NHLS has increased its public visibility during the past financial year. This increase was mainly due to the emergence of COVID-19 in South Africa. The Communication Department undertook various activities in an effort to share information about what the organisation does, as well as why, how and for whom. This was done through various media houses in South Africa, including the international media.

Despite difficulties brought about by the pandemic, the work of the organisation was communicated effectively. As such, the NHLS claimed a share of advertising value equivalent (AVE) valued at R116 million, reaching over 632 million citizens in South Africa.

Medium	Count of headline	Sum of AVE	Sum of reach
Broadcast	334	12 723 389	392 579 433
Online	1 260	51 966 827	218 486 351
Print	885	51 463 341	21 241 242
Total	**2 479**	**116 153 557**	**632 307 026**



Despite negative publicity in the media, the department focused on affirming the role of the NHLS in the country. Critical to the department's role is ensuring that all stakeholders are informed about the work of the NHLS. It needs to ensure that it has an interactive internal communications environment and builds a cohesive organisational culture.

Events

Launch of mobile units

The Communication Department organised and delivered the launch of 60 new mobile laboratories. The vehicles were unveiled to the media by the Minister of Health, Dr Zwelini Mkhize, the then Gauteng MEC for Health, Dr Bandile Masuku, and the Chairperson of the NHLS Board, Prof Eric Buch.

Orlando Pirates, Kaizer Chiefs and Multichoice Group donation

The department organised and hosted the presentation of personal protective equipment to the organisation donated by two of Soweto's soccer giants, Kaizer Chiefs and Orlando Pirates, in collaboration with the Multichoice Group.

The South African Red Cross Society and Absa donation

The department was instrumental in making sure that the presentation of two mobile units donated to the NHLS by the South African Red Cross Society, in partnership with Absa, on 10 December 2020, was delivered professionally.

Total South Africa donation

The department facilitated the presentation of fuel cards for the NHLS' 67 mobile laboratory units donated by Total South Africa. These mobile units have been deployed nationwide to provide screening, sampling and testing support to the provincial departments of Health in their efforts to combat COVID-19.

Internal communication

An interactive internal communication environment and a cohesive organisational culture are pivotal to the department's success. It facilitated regular messaging for the CEO to keep staff informed and to boost morale. The focus for the next financial year will be on implementing the Internal Communication Strategy by running a campaign to rebuild the organisation's reputation.

COVID-19 awareness

The spread of COVID-19 has left businesses trying to navigate unchartered territory. As such, the Communication Department developed posters about COVID-19 to help employees stay informed. These posters were placed in common areas, and some were mailed directly to employees.

Other services within the department

Customer care and general enquiries

The department is responsible for managing general enquiries for the organisation. External stakeholders and the general public send their enquiries to a general enquiries email address, and the Communication Department directs questions to the relevant departments. The turnaround time for feedback is 24 hours. During the year under review, approximately 558 general enquiries were recorded. The majority of these enquiries were related to COVID-19, accounts, paternity testing and TrakCare.

2.7 Performance information by subsidiary

2.7.1 South African Vaccine Producers

Megan Saffer
Director

Introduction

COVID-19 will be synonymous with 2020 for decades to come as it meant a total shutdown across many sectors for most of the year. While SAVP was, for the most part, able to continue within normal parameters, it experienced many challenges. Its sale of antivenom for the financial year was 13.75% lower than the previous year. However, the supply of boomslang antivenom increased by 46%.

The decline in sales can be attributed to delays in receiving imported raw material due to COVID-19 flight groundings. This was exacerbated by the Procurement Department's requirements for order approvals for consumables, as well as maintenance repairs. This impacted on all divisions within SAVP.

The subsidiary has a significant back-order list for antivenom sales as, at the end of March 2021, it is planning major upgrades to its production areas in line with WHO requirements for antivenom processing. The current facility is more than 30 years old and is no longer compliant with Good Manufacturing Practice regulations.

SAVP Small Animal Unit

The beginning of 2021 saw some reopening in the vaccines sector, but this was still hampered by the fact that the unit relies on air transport to get animals shipped to other provinces, and with South African Airways being grounded for the foreseeable future, the unit still had little to offer its customers. Clinvet in Bloemfontein has been the only external laboratory outside of Gauteng to make use of the SAVP's animals. They have driven up on a number of occasions to collect animals.

The unit had a query from an external laboratory regarding the supply of hamsters for COVID-19 research, but these plans are still in the early stages and nothing has yet been decided. In-house testing has remained relatively unchanged.

Renovations for SPF1 have been completed and will be put into operation in the new financial year.

Stables

The SAVP's stabling/paddocks are undergoing the following renovations:

- A tender is pending to repair the stable doors (now at award stage).
- It is necessary to pave around the stables due to the extremely muddy conditions experienced in the rainy season, and to expand the grazing camps and install an irrigation system.

PART C
GOVERNANCE

Adv. Mpho Mphelo
Company Secretary

3.1 Introduction

The NHLS ensures that its processes and practices are reviewed on an ongoing basis to ensure compliance with legal obligations, the use of funds in an economic, efficient and effective manner, and adherence to good corporate governance practices. Processes and practices are characterised by reporting on economic, environmental and social responsibilities. Such reporting is underpinned by the principles of openness, integrity and accountability, and is an inclusive approach that recognises the importance of all stakeholders with respect to the viability and sustainability of the NHLS.

Corporate governance is concerned with structures and processes for decision making, accountability, control and behaviour, beginning at the top level of the organisation. Corporate governance sets the tone for behaviour down to the lowest levels of the organisation.

3.2 Parliamentary Portfolio Committee

The Parliamentary Portfolio Committee on Health exercises oversight over the service delivery performance of the public entities reporting to the DoH. The NHLS appeared before the Parliamentary Portfolio Committee on Health on the dates set out below:

Date	Parliamentary Structure	Activity/ Focus
10 March 2021	Portfolio Committee on Health	Presentation of the 2019/20 Annual Financial Statements and Annual Report .
6 May 2021	Portfolio Committee on Health	Presentation of the Strategic Plan, Annual Performance Plan and Budget for the period 2021.

3.3 Report of the Accounting Authority

The Accounting Authority submits its report for the financial year ended 31 March 2021.

Statement of commitment

The Accounting Authority is committed to business integrity, transparency and professionalism in all its activities. As part of this commitment, the Accounting Authority supports the highest standards of corporate governance and the ongoing development of best practice.

The mandate of the Board

The mandate of the NHLS Board is set out in the NHLS Act and has been encapsulated in the NHLS Board Charter. The mandate of the Board, as set out in the Board Charter, is aligned to the requirements stipulated by the Protocol on Governance in Public Entities.

Independence of the Board

Board members are appointed by the Minister of Health. The Board considers submissions and recommendations made by management and makes independent decisions based on their fiduciary responsibilities and the strategic direction of the service. The various sub-committees of the board meet independently and then report back to the Board. Each committee has a formal charter that clearly defines its roles and responsibilities. The Audit and Risk Committee regularly meets individually with the external and internal auditors. Furthermore, the Board, its committees and individual Board members may engage independent counsel and advisors upon request and at the discretion of the Board.

Board composition

The Accounting Authority is a unitary board comprising a majority of non-executive members. The members of the Board are appointed by the Minister in accordance with section 7 of the NHLS Act. In terms of the NHLS Act, Act No. 37 of 2000, the Board should comprise 22 members, including the CEO, Chairperson and Vice Chairperson of the Board. In terms of section 9 of the NHLS Act, the Minister of Health appoints a Chairperson and a Vice Chairperson.

The members of the entity during the year under review are as follows:

	Name	Constituency	Date of appointment	Term end	Chairpersonship/ position in the NHLS
1	Prof Eric Buch (Chairperson)	Minister of Health	1 January 2017 Re-appointed 1 May 2021	1 May 2024	Board and GSEC
2	Prof Jeffery Mphahlele	Minister of Health	8 May 2020	8 May 2023	
3	Mr Ben Durham	Department of Science and Innovation	1 November 2014 Re-appointed 1 February 2018	31 January 2021	
4	Dr Gerhard Goosen	Mpumalanga Province	1 November 2015 Re-appointed 1 November 2018	1 November 2021	Acting Chair: FinCom
5	Mr Ian Van der Merwe	Department of Health	1 February 2018	31 January 2021	FinCom
6	Dr Kamy Chetty	CEO	4 October 2017		EXCO/ OPCO
7	Dr Balekile Mzangwa	Free State Province	18 November 2016 Re-appointed 18 January 2020	18 January 2023	
8	Mr Jonathan Mallett	Northern Cape Province	18 January 2020	18 January 2023	
9	Ms Sphiwe Mayinga	Public Nominee: Legal	20 April 2017 Re-appointed 8 May 2020	8 May 2023	RHRC
10	Dr Mary Ross	Minister of Health	1 September 2015 Re-appointed 1 4 September 2018	14 September 2021	RIC
11	Ms Nicolene Van der Westhuizen	Western Cape Province	1 May 2018	1 May 2021	
12	Mr Michael Shingange	Organised Labour (NEHAWU)	1 February 2015 Re-appointed 1 February 2018	1 February 2021	
13	Prof Larry Obi	Council on Higher Education	20 April 2017	20 April 2020	
14	Prof Thanyani Mariba	Limpopo Province	18 January 2020	18 January 2023	NAPC
15	Dr Siseko Martin	Eastern Cape Province	8 May 2020	8 May 2023	
16	Dr Naledzani Ramalivhana	Public Nominee: Health Research/Epidemiology	8 May 2020	8 May 2023	

	Name	Constituency	Date of appointment	Term end	Chairpersonship/ position in the NHLS
17	Mr Michael Sachs	Public Nominee: Economics, Financial Matters/Accounting	8 May 2020	8 May 2023	ARC
18	Prof Mpho Kgomo	Council on Higher Education	8 May 2020	8 May 2023	
19	Mr Koena Nkoko	South African Local Government Association	8 May 2020	8 May 2023	
20	Dr Lesley Bamford	National Department of Health	8 May 2020	8 May 2023	

Board member qualifications and external directorships

The NHLS Board members have the relevant skills, knowledge and experience to bring judgement to bear on the business of the NHLS. In situations where Board members may lack experience, detailed induction, and formal mentoring and support programmes are implemented. The Chairperson, together with the Board, have carefully considered outside chairpersonships that members hold. The relative size and complexity of companies in question have been considered. The Board members are satisfied that they have the ability and capacity to discharge their duties.

The qualifications and external directorships of NHLS Board members are disclosed in the table below:

Name	Qualifications and external directorships
Prof Eric Buch	**Qualifications:** MBBCh, MSc Med, FFCH(CM)(SA), DTM&H, DOH **Directorships:** Colleges of Medicine of South Africa NPC
Prof Jeffrey Mphahlele	**Qualifications:** BSc, BSc Med Hons, MSc, PhD **Directorships:** CEPI, EDCTP, GloPID-R, SAHPRA and Poliomyelitis Research Foundation NPC Deputy Vice- Chancellor: Research and Innovation, North-West University
Prof Mary Ross	**Qualifications:** BSc Hons, MBChB, Diploma (Datametrics), Diploma (Health Admin, DTM&H, DPH, DOH, FCPHM, FOM (UK), FPH (UK), FFTM (RCP&S) (Glasgow), FACTM (Australia) **Directorships:** None
Mr Ben Durham	**Qualifications:** MSc, BSc Hons, BSc, currently pursing PhD in Technology and Innovation Management **Directorships:** None
Mr Michael Shingange	**Qualifications:** Certificate in Negotiating Skills, Diploma in Trade Union Movement, Certificate in Governance **Directorships:** First Deputy President NEHAWU
Dr Gerhard Goosen	**Qualifications:** MBChB, Diploma in Obstetrics (SA) **Directorships:** ALENTI 25 (not for profit)
Dr Balekile E Mzangwa	**Qualifications:** MBChB **Directorships:** None
Mr Ian van der Merwe	**Qualifications:** BCom, BCom Honours, Master in Business Administration **Directorships:** None
Ms Sphiwe Mayinga	**Qualifications:** Masters in Business Administration, BProc, LLB, LLM, MAP, SLDP, Advanced Banking Law, Corporate Governance, Compliance Management **Directorships:** Tiyisela Construction, Overberg Water Board (Chairperson of the Human Resources Remuneration and Ethics Committee)
Prof Lawrence Obi	**Qualifications:** BSc Honours, MSc, PhD **Directorships:** None
Dr Kamy Chetty	**Qualifications:** MBChB, MSc URP, FFCH, BSc Honours (Epidemiology), Diploma in Occupational Health **Directorships:** Hospice Wits

Name	Qualifications and external directorships
Mr Jonathan Mallett	**Qualifications:** National Certificate in Medical Laboratories, National Diploma in Medical Laboratories, BTech, Advanced Health Management Certificate, BA **Directorships:** None
Ms Nicolene Van der Westhuizen	**Qualifications:** National Diploma in Clinical Pathology **Directorships:** None
Prof Thanyani Mariba	**Qualifications:** MBChB, FCP (SA), FRCP (London) **Directorships:** None
Dr Siseko Martin	**Qualifications:** BSc, BSc Honours, MBChB, Dip (DTM&H), FCPath, MMed **Directorships:** Dietrich Voigt Mia, Dr WJH Vermark Inc.
Dr Naledzani Ramalivhana	**Qualifications:** Diploma in Personnel and Training Management, Advanced Diploma in Occupational Health and Safety, National Diploma in Biomedical Technology, BSc Honours, MPH, MSc, PhD **Directorships:** Afroherbal Science Laboratories
Mr Michael Sachs	**Qualifications:** MSc (Economics), MPA (International Development) **Directorships:** NED- PILO (registered non-profit company)
Prof Mpho Kgomo	**Qualifications:** MBChB, FCP (SA), Gastroenterology, PhD **Directorships:** Styleprop (Pty) Ltd, Kgomo Family Trust, Holografix, Kgomo Inc, Head Clinical Unit (UP), SAGES
Mr Koena Nkoko	**Qualifications:** Diploma in Comprehensive Nursing, Advanced Diploma in Management, Postgraduate Diploma in Health Management, BTech OHN and Nursing Management, MPH, Master in Business Administration **Directorships:** None
Dr Lesley Bamford	**Qualifications:** MBChB, BSocSci, FCP, PhD **Directorships:** None

Changes in Board membership

Upon the expiration of a committee member's term of office as a member of the Accounting Authority, the member may be eligible for re-appointment for a further term of office provided that no committee member may be appointed for more than two consecutive terms to serve in the same committee. The table below indicates the changes to Board membership that took place during the financial year under review:

Name	Constituency/ representing	Date of appointment/ * reappointment	Date of resignation/ * retirement
Prof Eric Buch	Minister of Health	1 May 2021	30 April 2021
Prof Jeffrey Mphahlele	Minister of Health	8 May 2020	
Mr Ben Durham	Department of Science and Innovation	1 February 2018	31 January 2021
Mr Ian van der Merwe	Department of Health	1 February 2018	31 January 2021
Ms Sphiwe Mayinga	Public nominee: Legal	Re-appointed 8 May 2020	
Mr Michael Shingange	Organised Labour	Re-appointed 1 February 2018	1 February 2021
Dr Siseko Martin	Eastern Cape Province	8 May 2020	
Dr Naledzani Ramalivhana	Public nominee: Health Research/ Epidemiology	8 May 2020	
Mr Michael Sachs	Public nominee: Economics, Financial Matters/Accounting	8 May 2020	
Prof Mpho Kgomo	Council on Higher Education	8 May 2020	
Mr Koena Nkoko	South African Local Government Organisation	8 May 2020	
Dr Lesley Bamford	Department of Health	8 May 2020	
Prof Lawrence Obi	Council on Higher Education	20 April 2017	20 April 2020

Committees of the Board

The Board, as the Accounting Authority, takes full ownership of the overall decision making across the entity to ensure that it retains proper direction and control of the NHLS. The Board has delegated certain powers to the CEO and to management, but has reserved certain powers exclusively for the Board. These are set out in the Board Charter.

The Board has also appointed several committees to help it meet these responsibilities. Delegating various functions and authorities to committees and management, however, does not absolve the Board and its directors of their duties and responsibilities.

The Board has delegated certain functions without abdicating its own responsibilities to the following committees:

- Audit and Risk Committee (ARC)
- Remuneration and Human Resources Committee (RHRC)
- Governance, Social and Ethics Committee (GSEC) (ad hoc committee)
- Finance Committee (FinCom)
- National Academic and Pathology Committee (NAPC)
- Research and Innovation Committee (RIC)
- Executive Management Committee (EXCO)

The various committees of the Board each have formal terms of reference embodied into a charter that further defines the mandates, roles and responsibilities of each committee. The charters are reviewed and updated on an annual basis, where required.

The NHLS Board is governed by the NHLS Act (Act No. 37 of 2000) and the NHLS Rules made in terms of the Act. The Board complies with the PFMA. In addition, the NHLS Board subscribes to the terms of the King III Code of Corporate Governance.

In the period under review, the Board complied with its terms of reference, as detailed in the NHLS Rules. In addition, the Board has provided strategic direction to the organisation, as required by King III.

Minutes of meetings were made and entered in the minute book as a true and accurate representation of what transpired at the meetings.

The majority of the members of the Board attended the meetings for the year. Board resolutions were captured in the Board Resolution File.

Board meeting attendance

The Board meets on pre-arranged dates at least once a quarter and at other times as deemed necessary. The Board holds annual workshops to review strategy and to conduct annual risk assessment. During the past 12 months, the Board convened 25 times (including special meetings). Due to the Covid-19 pandemic and the nature of the service offered by the organisation, it became necessary for the board to meet 25 times in order to deal with urgent and important issues in furtherance of the mandate of the organisation. The NHLS Board is required to hold at least four meetings a year. Only members of the Board voted at its meetings and all its decisions were arrived at by consensus. In each of those meetings, the quorum of the meeting was met. In each meeting, members were given the opportunity to declare any personal conflict of interest in order to be recused from the deliberation of the matter in which a member was involved.

The table below and accompanying legend illustrates meeting attendance of Board members for the financial year:

Attendance of Board meetings for the year 1 April 2020 to 31 March 2021

Attendance of Board meetings for the year 1 April 2020 to 31 March 2021																									
Name	01/04/ 2020	28/04/ 2020	15/05/ 2020	27/05/ 2020	25/06/ 2020	10/07/ 2020	29/07/ 2020	30/07/ 2020	20/08/ 2020	10/09/ 2020	21/09/ 2020	23/09/ 2020	29/09/ 2020	29/09/ 2020	20/10/ 2020	26/10/ 2020	10/11/ 2020	16/11/ 2020	25/11/ 2020	26/11/ 2020	20/01/ 2021	21/01/ 2021	01/02/ 2021	03/03/ 2021	04/03 2021	TOTAL
Prof Eric Buch	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	25
Prof Jeffrey Mphahlele	n/m	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	√	√	A	√	√	√	√	√	√	22
Prof Mary Ross	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	25
Dr Gerhard Goosen	√	√	√	√	√	√	√	√	A	√	√	√	√	√	√	√	A	√	√	√	√	√	A	√	√	22
Mr Michael Shingange	√	√	√	√	A	A	√	√	√	√	√	√	A	√	√	√	√	A	√	A	√	A	√	√	√	19
Mr Ian Van der Merwe	A	√	√	√	A	√	√	A	A	√	√	√	√	√	A	√	A	A	√	√	√	√	√	√	√	17
Dr Balekile Mzangwa	√	√	A	√	A	A	A	√	√	√	√	√	A	√	√	√	A	√	A	√	A	√	√	√	A	17
Mrs Nicolene Van der Westhuizen	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	25
Mr Ben Durham	√	√	√	√	A	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	√	√	√	√	√	12
Ms Sphiwe Mayinga	√	n/m	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	A	√	A	√	√	√	√	√	21
Prof Larry Obi	√	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	A	√	√	√	√	√	√	√	A	A	9
Prof Thanyani Mariba	√	√	√	√	A	√	√	√	√	A	A	√	√	√	√	√	A	√	√	√	√	A	√	√	√	12
Mr Jonathan Mallett	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	A	√	√	√	22
Dr Naledzani Ramalivhana	n/m	n/m	n/m	n/m	A	√	√	√	√	√	√	A	A	√	√	√	√	√	A	√	√	√	√	A	A	15
Mr Michael Sachs	n/m	n/m	n/m	n/m	√	A	√	√	√	√	√	√	√	√	√	√	√	√	A	A	√	√	A	√	√	17
Prof Mpho Kgomo	n/m	n/m	n/m	n/m	A	√	√	√	√	√	√	√	√	√	A	√	√	√	A	A	A	A	A	A	A	12
Dr Lesley Bamford	n/m	n/m	n/m	n/m	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	A	A	A	√	√	14
Mr Koena Nkoko	n/m	n/m	n/m	n/m	√	√	√	√	√	√	A	A	A	A	√	A	√	√	√	√	√	√	√	√	√	11
Dr Siseko Martin	n/m	n/m	n/m	n/m	√	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	√	√	√	√	√	19
Dr Kamy Chetty	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	25
Total number of meetings																										

Total number of meetings: 15 + 10 = 25

LEGEND:

- **= Present * = Appointed A = Apology B = Absent n/m = Not a member % = Retired/resigned**

Organisational group profile

Business and operations

The NHLS is a national public entity established in terms of the NHLS Act, Act No. 37 of 2000, to provide quality, affordable and sustainable health laboratory and related public health services.

The NHLS is the main provider of clinical support services to the national, provincial and local departments of health through its countrywide network of quality-assured diagnostic laboratories. The NHLS also provides surveillance support for communicable diseases, occupational health and cancer, and thus endeavours to align its strategy to both the DoH's priorities and the national and regional burden of disease.

The NHLS is managed according to the provisions of the NHLS Act, Act No. 37 of 2000, as well as the NHLS Rules, gazetted in July 2007, and the PFMA. It is a state-owned organisation governed by a Board and a CEO. The NHLS has a clear organisational structure consisting of a Head Office in Sandringham, Johannesburg, six regions (Limpopo and Mpumalanga, KwaZulu-Natal, Eastern Cape, Western and Northern Cape, Free State and North West, and Gauteng) and three institutes (the National Institute for Communicable Diseases (NICD), NIOH and NCR). Each area is headed by a Business Area Manager who reports directly to a Chief Operations Officer (COO). The establishment of six regions is designed to ensure that the NHLS plans, agrees, budgets and monitors laboratory services jointly with provincial health partners with the intention of laboratory services being seen and accepted as part of the public health delivery system. Point-of-care testing is increasingly being used to speed up diagnosis within the health facility. The NHLS recognises the value that POCT plays.

The NHLS delivers services throughout the public sector, from primary healthcare level to tertiary or quaternary hospitals. The level of complexity and sophistication of services increases from the peripheral laboratories to the central urban laboratories (with specialised surveillance infrastructure existing at isolated sites). The legacy of apartheid has left the health laboratory services in South Africa concentrated mainly in Gauteng, KwaZulu-Natal and the Western Cape, in line with the spread of the previously advantaged institutions of higher learning.

Public sector laboratories are situated within the health facilities owned by the Department of Health, and, in some cases, universities. Therefore, the condition of the infrastructure depends on the quality of the health facility in which the laboratory is located. Great disparities still exist between urban and rural facilities. Some central, urban facilities are currently undergoing upgrades through the Hospital Revitalisation Programme. However, many remote rural facilities still require access to basic services.

SAVP

The SAVP is a wholly owned subsidiary of the NHLS and provides the following services:

- The manufacture of biologicals, namely anti-venom, which includes the following:
  - Polyvalent antivenom
  - Echis antivenom
  - Boomslang antivenom
  - Spider antivenom
  - Scorpion antivenom
- Safety testing for pharmaceutical companies;
- Research on routine products authorised via the Animal Ethics Committee involving animals;
- Preparation of horse and sheep serum; and
- Preparation and sampling of horse blood.

Governance, Commitments and Stakeholder Engagement

Legislative and Governance Framework

The NHLS is required to comply with the following, among others:

- National Health Laboratory Service Act, Act No. 37 of 2000
- General Rules made in terms of section 27 of the NHLS Act
- National Health Act, Act No. 61 of 2003
- Companies Act, Act No. 71 of 2008
- Protocol on Good Corporate Governance in the Public Sector
- Public Finance Management Act, Act No. 1 of 1999 (as amended)
- Treasury Regulations issued in terms of the PFMA, 1999
- Preferential Procurement Framework Act, Act No. 5 of 2000
- Relevant legislation applicable to the health sector
- King IV Code on Good Corporate Governance
- Constitution of the Republic of South Africa, Act No. 108 of 1996

Role and function of the Accounting Authority

The Board is the Accounting Authority of the NHLS in terms of the NHLS Act and the PFMA. The Board is scheduled to meet on a quarterly basis and is responsible for providing strategic direction and leadership, ensuring good corporate governance and ethics, determining policy, agreeing on performance criteria, and delegating the detailed planning and implementation of policy to EXCO.

The Board should comprise 22 members, including the CEO, Chairperson and Vice Chairperson of the Board (21 members are non-executive members, and one member is an executive). The Board evaluates and monitors management's compliance with policy and achievements against objectives. A structured approached is followed for delegation, reporting and accountability, which includes reliance on various Board committees. The Chairperson guides and monitors the input and contribution of the Board members.

The Board has unlimited access to professional advice on matters concerning the affairs of the economic entity, at the economic entity's expense. The Board has approved a Code of Corporate Practice and Conduct, which includes the terms of reference that provide guidance to the Board members in discharging their duties and responsibilities.

The Board evaluates its effectiveness on an annual basis and formulates plans to mitigate any shortcomings identified by the evaluation process.

Chairperson and Chief Executive

The Chairperson is a non-executive and independent director (as recommended by good corporate governance practices). The Chairperson is a standing member of all committees of the Board. The roles of Chairperson and Chief Executive are separate, with responsibilities divided between them, so that no individual has unfettered powers of discretion.

Remuneration and Human Resources Committee

In terms of the NHLS Act, the RHRC is a committee of the Board, which serves to assist it with the performance of its functions and exercising of its powers. The Committee reports on employment equity, employee turnover, skills development and labour relations. As part of the continued professional development programme, the Board invites corporate governance experts, as recommended by the Institute of Directors, from time to time, to present topical matters and the latest developments in

corporate governance practices.

In terms of good corporate governance practices, the RHRC met on five separate occasions during the financial year. A joint RHRC and FinCom meeting was convened on 30 July 2020 to consider the financial position of the NHLS in response to union demands for an annual salary increase and changes in benefits.

Remuneration and Human Resources Committee meetings for the year 1 April 2020 to 31 March 2021

Remuneration and Human Resources Committee meetings for the year 1 April 2020 to 31 March 2021						
	Meeting dates					
Name	**15/07/2020**	**16/09/2020**	**29/10/2020**	**09/12/2020**	**16/02/2021**	**TOTAL**
Ms Sphiwe Mayinga (Chairperson)	√	√	√	√	√	**5**
Dr Balekile Mzangwa (Vice- Chair)	√	√	√	√	√	**5**
Dr Gerhard Goosen (Member)	√	√	A	√	√	**4**
Mr Michael Shingange (Member)	√	√	√	A	n/m	**3**
Dr Lesley Bamford (Member)	√	√	√	A	A	**3**
Mr Koena Nkoko (Member)	A	A	√	A	A	**1**
Dr Kamy Chetty (CEO)	√	√	√	√	√	**5**
Total number of meetings	**5**					

• Mr Michael Shingange term of office expired on 01 February 2021.

LEGEND:

√ = Present * = Appointed √ A = Apology ** = Appointed √ B = Absent * = Appointed √ n/m = Not a member % = Retired/ Resigned**

The Executive Committee

In terms of the NHLS Act, The Accounting Authority has appointed an Executive Management Committee (EXCO) which consists of the CEO, who acts as Chairperson, and regional executive managers and executive managers from support services. The EXCO is responsible for the management of the NHLS in accordance with the policy of the NHLS and assists with performance of the Accounting Authority's functions and the exercise of its powers.

Executive/Operational Committee

During the period under review, the Executive/Operational Committee met 31 times.

Executive/Operational Committee for the year 1 April 2020 to 31 March 2021

Executive/Operational Committee for the year 1 April 2020 to 31 March 2021																																
Name	06/04/ 2020	16/04/ 2020	21/04/ 2020	29/04/ 2020	04/05/ 2020	11/05/ 2020	18/05/ 2020	25/05/ 2020	01/06/ 2020	08/06 2020	22/06 2020	29/06/ 2020	06/07/ 2020	13/07/ 2020	20/07/ 2020	03/08/ 2020	17/08/ 2020	31/08/ 2020	14/09/ 2021	28/09/ 2020	05/10/ 2020	12/10/ 2020	02/11/ 2020	10/11/ 2020	08/12/ 2020	14/12/ 2020	07.01/ 2021	11.01/ 2021	02/02/ 2021	08/02/ 2021	08/03/ 2021	TOTAL
Dr Kamy Chetty (Chairperson)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	31
Mr Michael Sass (CFO)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	n/m	n/m	n/m	n/m	n/m	n/m	n/m	22
Mr Jonas Shai (Acting CFO)	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	√	√	A	A	√	3
Mr Sibongiseni Hlongwane (CIO)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	31
Prof Koleka Mlisana (AARQA Executive)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	30
Prof Lynn Morris (Interim Director NICD)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	√	√	A	√	√	A	A	n/m	n/m	n/m	n/m	n/m	n/m	n/m	20
Prof Adrian Puren (Interim Director NICD)	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	A	√	√	√	√	√	√	6
Dr Spo Kgalamono (Acting NIOH Director)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	n/m	n/m	n/m	n/m	n/m	n/m	√	√	√	√	√	24
Dr Muzimkhulu Zungu (Acting NIOH Director)	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	√	√	√	A	√	√	√	n/m	n/m	n/m	n/m	n/m	6
Dr Mojaki Mosia (HR Executive)	√	√	√	A	√	√	√	A	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	6
Adv Mpho Mphelo (Acting HR Executive)	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	√	√	√	√	√	√	A	√	√	√	A	√	√	√	√	√	n/m	n/m	n/m	n/m	n/m	n/m	n/m	14
Mr Jone Mofokeng (Acting HR Executive)	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	√	√	√	√	√	√	√	√	√	√	√	11
Adv Mpho Mphelo (Company Secretary)	√	A	√	√	√	√	√	√	√	√	√	√	√	A	A	√	√	√	A	√	√	√	√	√	√	√	√	√	√	√	√	27
Prof Wendy Stevens (NPP Executive)	√	√	√	√	√	√	√	√	A	A	√	√	√	√	√	A	√	√	A	√	√	√	A	A	√	√	√	√	√	√	√	25
Mr Jone Mofokeng (Area Manager: Free State / North West)	√	√	√	A	√	√	√	√	A	A	A	√	√	√	√	√	√	√	A	A	A	√	√	√	√	√	√	√	√	√	√	24
Ms Tabita Makula (Area Manager: Eastern Cape)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	√	√	√	√	√	30
Mr Sibulele Bandezi (Area Manager: KwaZulu-Natal)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	A	A	√	√	√	√	√	√	√	√	√	28
Mr Jacob Lebudi (Area Manager: Limpopo / Mpumalanga)	A	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	√	√	√	√	A	√	√	√	√	29
Ms Nasima Mohamed (Area Manager: Northern Cape / Western Cape)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	A	√	√	√	√	√	√	√	A	29
Mr Bahule Motlonye (Area Manager: Gauteng)	√	√	√	√	√	√	√	√	√	√	A	A	√	√	√	√	√	√	√	√	A	√	A	√	√	√	√	√	√	√	√	27
TOTAL	11																															

Total number of meetings: 11 + 10 + 10 = 31

LEGEND:

√ = Present A = Apology n/m = Not a member

Finance Committee

The Finance Committee assists the Accounting Authority in fulfilling its oversight responsibilities on an ongoing basis for matters relating to the financial practices and condition of the economic entity by reviewing the economic entity's financial policies and procedures, keeping informed of the economic entity's financial conditions, requirements for funds, and access to liquidity, and considering and advising the Accounting Authority concerning its sources and use of funds.

In terms of good corporate governance practices, the Financial Committee met on five separate occasions during the financial year. Two special meetings were convened to consider procurement and finance submissions, which required urgent attention and Board approval.

Finance Committee meetings for the year 1 April 2020 to 31 March 2021

	MEETING DATES					
Name	**06/11/2020**	**24/11/2020**	**25/11/2020**	**04/02/2021**	**02/03/2021**	**TOTAL**
Mr Ian Van der Merwe (Chairperson)	√	√	√	n/m	n/m	**3**
Dr Gerhard Goosen (Vice- Chair)	√	√	√	√	A	**4**
Dr Balekile Mzangwa (Member)	A	A	A	√	√	**2**
Mr Michael Shingange (Member)	A	A	√	n/m	n/m	**1**
Mr Michael Sachs (Member)	A	√	√	√	√	**4**
Dr Naledzani Ramalivhana (Member)	√	√	√	√	√	**5**
Dr Kamy Chetty (CEO)	√	√	√	√	√	**5**
Total number of meetings						

* Mr Ian van der Merwe's term of office expired on 31 January 2021.
* Mr Michael Shingange's term of office expired on 1 February 2021.

LEGEND:

√ = Present * = Appointed A = Apology % = Retired/Resigned B = Absent n/m = Not a member

Audit and Risk Committee

In keeping with Treasury Regulation 27 of the PFMA, the Board appointed an Audit and Risk Committee to assist in the discharge of its duties by reviewing and reporting on the governance responsibilities of the Board and the NHLS. The terms of reference of the Audit and Risk Committee, its duties and functions, its composition and its modus operandi have been approved by the Board.

The Committee met twice during the period under review.

Audit and Risk Committee meetings for the year 1 April 2020 to 31 March 2021

Name	**24/11/2020**	**27/01/2021**	**TOTAL**
Mr Michael Sachs (Chairperson ARC)	√	√	**2**
Mr Ian Van der Merwe (Member)	A	A	**0**
Ms Sphiwe Mayinga (Member)	A	√	**1**
Mr Jonathan Mallett (Member)	√	A	**1**
Mr Koena Nkoko (Member)	A	√	**1**
Dr Naledzani Ramalivhana (Member)	A	√	**1**
Mr Goolam Manack (Independent Member)	√	A	**1**
Dr Kamy Chetty (CEO)	√	√	**2**
Total number of meetings	**2**		

LEGEND:

√ = Present A = Apology n/m = Not a member

Joint Audit and Risk Committee and Finance Committee

During the period under review, joint meetings of the Audit and Risk Committee and Finance Committee were convened. The meetings were convened for the committees to jointly consider the following:

- Unaudited annual financial statements for the financial year ended 31 March 2020 before they could be submitted to the external auditor for auditing
- Audited annual financial statements and external auditors' report for the financial year ended 31 March 2020 before they could be tabled to the Board for approval
- The NHLS' budget for 2021

During the period under review the joint Audit and Risk Committee and Finance Committee met five times.

Joint meetings of the Audit and Risk Committee and the Finance Committee for the year 1 April 2020 to 31 March 2021

	MEETING DATES					
Name	**26/05/2020**	**22/07/2020**	**08/09/2021**	**15/10/2020**	**20/10/2020**	**TOTAL**
Mr Ian Van der Merwe (Chairperson: Finance Committee)	√	√	√	A	√	**4**
Mr Michael Sachs (Chairperson Audit Risk Committee)	n/m	√	√	√	√	**4**
Dr Gerhard Goosen (Vice- Chairperson: Finance Committee)	√	√	√	√	√	**5**
Dr Balekile Mzangwa (FinCom member)	√	√	√	√	A	**4**
Mr Koena Nkoko (FinCom / ARC member)	n/m	A	√	√	√	**3**
Dr Naledzani Ramalivhana (FinCom / ARC member)	n/m	√	√	√	A	**3**
Mr Michael Shingange (FinCom member)	√	√	√	√	A	**4**
Ms Sphiwe Mayinga (ARC member)	n/m	√	A	√	A	**2**
Mr Jonathan Mallett (ARC member)	√	√	A	√	√	**4**
Mr Goolam Manack (Independent Member)	√	√	√	√	√	**5**
Dr Kamy Chetty (CEO)	√	√	√	√	√	**5**
Total number of meetings	**5**					

• Mr Michael Sachs, Mr Koena Nkoko, Ms Sphiwe Mayinga and Naledzani Ramalivhana were appointed to serve as members of ARC/ FinCom with effect from 28 May 2020.

LEGEND: -

n/m = Not a member √ = Present A = Apology

National Academic and Pathology Committee

The functions of the National Academic and Pathology Committee (NAPC) are to facilitate the formulation of policy with regard to the following:

- conduct of basic research in association or in partnership with any tertiary educational institution;
- cooperation with persons and institutions undertaking basic research in South Africa and in other countries through the exchange of scientific knowledge and the provision of access to the resources and specimens available to the NHLS;
- participation in joint research operations with government departments, universities, universities of technology, colleges, museums, scientific institutions and other persons;

- cooperation with educational authorities and scientific or technical societies or industrial institutions representing employers and employees for the promotion of the instruction and training of pathologists, technologists, technicians, scientists, researchers, technical experts and other supporting personnel in universities, universities of technology and colleges;
- any other matter as may be referred to the Committee from time to time by the Board;
- as some of its duties, the Committee shall monitor and manage the agreements entered into between the NHLS and each tertiary education institution, including the following:
- development of policies and guidelines to determine the number of registrars for each discipline and the distribution of registrar posts between the laboratories associated with each university health science faculty;
- development of policies and guidelines to determine the number of technologist training posts for each discipline and the distribution of posts between the laboratories identified for this purpose;
- Proposing guidelines relating to the part-time, honorary and guest appointment of employees of the NHLS by tertiary education institutions
- monitoring the guidelines for consultant appointments of personnel of tertiary education institutions in the NHLS as determined by the agreement between the NHLS and the universities;
- ensuring that the process of continuing professional development programmes provided by tertiary education institutions in the NHLS is used by NHLS employees to comply with career programme development requirements;
- reviewing and managing arrangements for research being undertaken by tertiary education institutions in the laboratories of the NHLS;
- advising the executive management on matters relating to indemnity for employees of the NHLS or a tertiary education institution working between the facilities of both partners;
- advising EXCO on matters relating to discipline of personnel of the NHLS or a tertiary education institution working between the facilities of both partners;
- Advising EXCO on financial matters, such as subsidies, bursaries and payment for academic services;
- monitoring and evaluating, and managing service-level agreements and performance measures;
- Advising, monitoring and evaluating the resolution of disputes if they should arise;
- ensuring the integrity of the process of managing partnerships;
- ensuring that professional ethics are adhered to; and
- ensuring that the NHLS complies with the requirements of the HPCSA in respect of registration requirements, ethics and conduct.

The Committee met on four separate occasions during the financial year.

NAPC meetings for the year 1 April 2020 to 31 March 2021

	MEETING DATES				
Name	**20/05/2020**	**06/08/2020**	**05/11/2020**	**10/02/2021**	**TOTAL**
Prof Thanyani Mariba (Chairperson)	√	√	√	√	**4**
Prof Jeffrey Mphahlele (Chairperson SC1)	n/m	√	√	√	**3**
Ms Nicolene van der Westhuizen (Chairperson SC1)	√	√	√	√	**4**
Prof Mary Ross (Member)	√	√	√	√	**4**
Mr Jonathan Mallett (Member)	n/m	√	A	A	**1**
Prof Mpho Kgomo (Member)	n/m	√	√	√	**3**
Dr Kamy Chetty (CEO)	√	√	√	√	**4**
Total number of meetings	**4**				

* Prof Jeffery Mphahlele was appointed as Chairperson of NAPC SC1 with effect from 28 May 2020.
* Mr Jonathan Mallett and Prof Mpho Kgomo were appointed to serve on the NAPC with effect from 28 May 2020.

LEGEND:
• = Present A = Apology n/m = Not a member

Governance and Social Ethics Committee

The Governance and Social Ethics Committee was established to assist the Board with the oversight of corporate governance, social and ethical matters and ensuring that the organisation is and remains a committed socially responsible corporate citizen. The commitment to sustainable development involves ensuring that the organisation conducts business in a manner that meets existing needs without knowingly compromising the ability of future generations to meet their needs. The Committee's primary role is to supplement, support, advise and provide guidance on the effectiveness or otherwise of management's efforts in respect of governance, social and ethics and sustainable development-related matters which, inter alia, include the following:

- safety;
- health and wellness, including occupational hygiene;
- environmental management;
- climate change;
- ethics management;
- corporate social investment;
- mine community development;
- stakeholder engagement; and
- protection of company assets.

The Committee shall do the following:

- Review and approve the policy, strategy and structure to manage governance, social and ethics issues in the organisation
- Oversee the monitoring, assessment and measurement of the organisation's activities relating to social and economic development, including the organisation's standing in terms of the goals and purposes of the following:
  - The 10 principles set out in the United Nations Global Compact
  - The Organisation for Economic Cooperation and Development (OECD)'s recommendations regarding corruption
  - The Employment Equity Act
  - The Broad-based Black Economic Empowerment Act
- Oversee the monitoring, assessment and measurement of the organisation's activities relating to good corporate citizenship, including the organisation's promotion of equality, prevention of unfair discrimination, addressing of corruption, contribution to the development of communities in which its activities are predominantly conducted or within which its services are predominantly marketed, and record sponsorships, donations and charitable giving
- Oversee the monitoring, assessment and measurement of the organisation's activities relating to the environment, health and public safety, including the impact of the organisation's activities and of its services
- Oversee the monitoring, assessment and measurement of the organisation's stakeholder relationships, including its advertising, public relations and compliance with consumer protection laws in order to ensure that the organisation adheres to its values
- Oversee the monitoring of the organisation's labour and employment, including its standing in terms of the International Labour Organisation Protocol on decent work and working conditions, the organisation's employment relationships, and its contribution to the educational development of its employees
- Review the adequacy and effectiveness of the organisation's engagement and interaction with its stakeholders
- Consider substantive national and international regulatory developments, as well as practice in the fields of social and ethics management
- Review and approve the policy and strategy pertaining to the organisation's programme of corporate social investment
- Determine clearly articulated ethical standards (Code of Ethics) and ensure that the organisation takes measures to achieve adherence to these in all aspects of the business, thus achieving a sustainable ethical corporate culture within the organisation
- Monitor that management develops and implements programmes, guidelines and practices congruent with its social and

ethics policies

- Review the material risks and liabilities relating to the provisions of the Code of Ethics, and ensure that such risks are managed as part of a risk management programme
- Obtain external assurance of the organisation's ethics performance on an annual basis, and facilitate the inclusion in the integrated report of an assurance statement related to the ethics performance of the organisation
- Ensure that management has allocated adequate resources to comply with social and ethics policies, codes of best practice and regulatory requirements

During the period under review the Committee met seven times. The Committee had to meet more often as it had to deal with matters relating to allegations of irregularities relating to the procurement of PPEs and related disciplinary proceedings against those implicated.

During the period under review, the Committee met seven times.

Governance and Social Ethics Committee meetings for the year 1 April 2020 to 31 March 2021

	Meeting dates							
Name	**19/11/ 2020**	**02/12/ 2020**	**07/12/ 2021**	**14/12/ 2020**	**14/01/ 2021**	**29/01/ 2020**	**01/03/ 2021**	**TOTAL**
Prof Eric Buch (Chairperson of the NHLS Board)	√	√	√	√	√	√	√	**7**
Prof Jeffrey Mphahlele (Vice-Chairperson of the NHLS Board)	√	A	A	√	√	√	√	**5**
Prof Thanyani Mariba (Chairperson NAPC)	n/m	n/m	n/m	n/m	n/m	n/m	√	**1**
Prof Mary Ross (Chairperson RIC)	n/m	n/m	n/m	n/m	n/m	n/m	√	**1**
Ms Sphiwe Mayinga (Chairperson RHRC)	A	A	A	√	√	√	√	**4**
Mr Michael Sachs (Chairperson ARC)	√	A	A	√	√	A	√	**4**
Dr Gerhard Goosen (Vice-Chairperson FIN)	n/m	n/m	n/m	n/m	n/m	n/m	√	**1**
Dr Balekile Mzangwa	√	√	√	√	A	√	√	**6**
Dr Kamy Chetty (CEO)	√	A	A	√	√	√	√	**5**
Total number of meetings	**7**							

LEGEND:

• = Present * = Appointed A = Apology % = Retired/resigned B = Absent n/m = Not a member

Research and Innovation Committee

The Committee was established as a vehicle for ensuring that the NHLS' research mandate receives attention at Board level. Members of the Research and Innovation Committee may be called on from time to time to interact with external stakeholders and funding agencies. The role of the Committee is to advise the NHLS Board and the NAPC on research policies, strategies, initiatives and innovation that promote the research interests of the organisation and that nurture and enable high-quality research.

The objectives of the Research and Innovation Committee are aligned with those stipulated in the South African Health Research Policy of 2001, the national DoH's 10-point plan and the National Health Research Committee (NHRC).

Research and Innovation Committee meetings for the year 1 April 2020 to 31 March 2021

	Meeting Dates				
Name	**18/05/2020**	**05/08/2020**	**04/11/2020**	**09/02/2021**	**TOTAL**
Prof Mary Ross (Chairperson)	√	√	√	√	**4**
Mr Ben Durham (Vice Chair)	√	√	√	n/m	**3**
Prof Thanyani Mariba (Chairperson Member)	√	√	√	√	**4**
Mrs Nicolene van der Westhuizen (Member)	n/m	√	√	√	**3**
Dr Naledzani Ramalivhana (Member)	n/m	√	√	√	**3**
Dr Siseko Martin (Member)	n/m	√	√	√	**3**
Dr Kamy Chetty (CEO)	√	√	√	√	**4**
Total number of meetings	**4**				

* Mr Ben Durham's term of office expired on 31 January 2021.

* Dr Siseko Martin, Dr Naledzani Ramalivhana and Mrs Nicolene Van der Westhuizen were appointed to serve as members of this Committee with effect from 28 May 2020.

LEGEND:

- **= Present * = Appointed A = Apology % = Retired/resigned B = Absent C = Not a member**

3.4 Company Secretary

The Company Secretary plays a critical role in providing secretarial and advisory services to the Board and its committees. Furthermore, the Company Secretary is a liaison officer between the management and the Board, and between the Board and the shareholder on issues relating to governance, thus giving effect to governance protocols. The Company Secretary is the custodian of the register of Board and Committee decisions.

The Company Secretary provides guidance to both the executives and the non-executive members of the Board in the discharge of their fiduciary duties and ensures that Board proceedings are carried out in accordance with the relevant legislative requirements.

The Company Secretary is well experienced and qualified to fulfil the following roles:

- induction of new Board members;
- providing Board members collectively and individually with guidance as to their duties, responsibilities and powers;
- making Board members aware of any law relevant to or affecting the entity;
- providing guidance to and advising the Board on ethical matters and good governance principles; and
- recording Board and Committees proceedings.

Board members have unlimited access to the advice and services of the Company Secretary.

3.5 Audit and Risk Committee Report

The committee is pleased to present its report for the financial year that ended 31 March 2021.

Audit and Risk Committee responsibility

The committee reports that appropriate formal Terms of reference was adopted in its charter, in line with the requirements of section 51(1)(a) (ii) of the PFMA and Treasury Regulation 27. The committee further reports that its affairs were conducted in compliance with this charter.

The effectiveness of internal control

The committee reviewed various reports prepared by the internal and external auditors on the adequacy and effectiveness of the control environment as well as on the Annual Financial Statements (AFS). The committees assessed the control environment based on the following three (3) parameters namely: **Satisfactory,** where business process controls were reported as both adequate and effective; **Weak,** where some controls within the business process were reported as ineffective and **Unsatisfactory,** where some controls within the business process were reported as both inadequate and ineffective. The committee assessment of internal control systems is depicted on the heat map below and is based on eight (8) business processes.

No	Business process	Control assessment		
1	Compliance		😐	
2	Financial health	☺		
3	Financial management		😐	
4	Human resources	☺		
5	Information technology			☹
6	Procurement and contract management			☹
7	Performance management	☺		
8	Oversight and monitoring	☺		

Heat map legend: Satisfactory Weak Unsatisfactory

The committee received commitment from management that they will improve the control environment for all processes that were assessed as weak and unsatisfactory. Furthermore, management committed to resolve all the previous reported findings that were not resolved at year end. The committee instructed Internal Audit Function to perform follow up audit to ensure that management has implemented corrective actions to address all reported audit findings and provide feedback to the committee during quarterly meetings.

Internal audit

The committee is satisfied with the role the internal audit function is playing in the organisation and acknowledges that the functions needs to be adequately capacitated and resourced in order to fulfil its responsibilities. The committee is satisfied that 93% of the internal audit reviews included in the approved Annual Internal Audit Plan were completed and only 7 % was differed to the 2021/2022 financial year. The committee reviewed the internal audit reports and heightened the need for management to address reported findings. The reports reviewed include amongst the following:

- Property, plant and equipment;
- Procurement and account payable;
- Contracts management;
- Payroll and human resources;
- Audit of performance information;
- Laboratory reviews;
- IT general controls review;
- IT service continuity review;
- Cybersecurity review;
- Tender Compliance reviews; and
- Follow-ups on reported audit findings.

Risk management

The responsibility for risk management resides with management at all levels with the Board playing an oversight role as such risk management is embedded throughout the organisation, from members of the Board to all employees. The approach followed by the NHLS is to ensure that significant risks are identified and managed.

The NHLS has a dedicated Risk Management and Internal Audit Department to coordinate the implementation of its risk management approach and strategy, as approved by the Board. The Board continues to discharge this responsibility through the ARC. The strategic and operational risks assessment workshops were facilitated during the financial year and the results thereof were reviewed by the ARC. The progress on implementation of strategic risks mitigation actions plan was submitted during quarterly meetings to enable the committee to evaluate the adequacy and effectiveness of these actions to mitigate identified risks. The committee is satisfied with the management action plan to mitigate identified risks.

Fraud and corruption

The anonymous tip off platforms for reporting fraud, corruption and unethical behaviours were operational during the financial year. These platforms are administered by the independent service provider. The committee received the final investigation reports with findings, conclusions and recommendations on the reported allegations during quarterly meetings. The committee received assurance from management that the recommendations of the investigation reports were being implemented.

The committee notes with concern the irregularities that took place during emergency procurement transactions that were undertaken during the outbreak of corona virus. The committee is satisfied by the disciplinary actions implemented by management. The committee was also satisfied with management action of reporting service providers that charged prices that were above National Treasury recommended prices to the Competition Commission for further investigation. The committee was informed by management that NHLS was assisting the Directorate for Priority Crime Investigation (Hawks) and provided information of some service providers that dealt with NHLS during emergency procurement which are being investigated by Hawks.

Quarterly reports

The committee appreciates the content and quality of quarterly reports prepared and issued by management of the NHLS during the year under review, but requested certain improvements to the reports. The committee is satisfied with the commitment from management to resolve this matter.

Competency of the Finance department

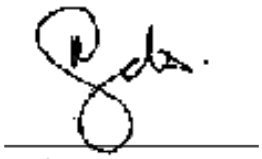
In compliance with governance principles 8. 59(f) of the King IV code of governance principles, the committee acknowledges that there are inadequate resources and competency gaps in the Finance Department. Management committed to correct the identified gaps in order to strengthen the skills and competency of the Finance Department.

Evaluation of the Group Annual Financial Statements

During the reporting year, the committee has reviewed the following:

- The audited Group AFS with the external auditors (Nexia SAB&T);
- Nexia SAB&T's management report and management's response thereto;
- Accounting policies and practices;
- The entity's compliance with legal and regulatory provisions; and
- Significant adjustments resulting from the external audit.

The committee concurs with and accepts the external auditors' report on the Group AFS and is of the opinion that the audited Group AFS should be accepted. Moreover, having had regard to its statutory and other responsibilities as well as all factors that may have an impact on the integrity of the financial statements, the committee agrees that the adoption of the going concern premise is appropriate in preparing the Group AFS for the 2020/2021 financial year. The committee therefore recommended the adoption of the Group AFS by the NHLS Board at the meeting held on the 5th of August 2021



Prof Michael Sachs

Chairperson: Audit and Risk Committee

PART D
HUMAN RESOURCES

4.1 Executive Summary

Jone Mofokeng
Acting HR Executive Manager

As at 31 March 2021, the NHLS had a total staff complement of 8 632, of which 7 057 (82%) were permanent and 1 227 (14%) fixed-term contracts. The majority of fixed-term contracts (796 or 9.2%) were appointed as a response to the COVID-19 pandemic's testing requirements and increased scope and volume of work, complicated by the high number of absenteeism due to staff being either positive or under quarantine.

The NHLS' total salary bill for the period under review increased by 7.7% to R4.2 billion, of which close to 46% was paid to health professionals such as pathologists, medical scientists, technologists and technicians, representing 35% of the total workforce.

Table 4.1: Personnel cost by programme, activity or objective

Programme/activity/ objective	Total Expenditure for the entity (R'000)	Personnel Expenditure (R'000)	Personnel exp. as a % of total exp. (R'000)	No. of employees	Average personnel cost per employee (R'000)
Total remuneration cost	R 11 802 966	R 4 202 399	36%	8632	486 902

The total annual salary bill or personnel expenditure for the 2020/21 financial year amounts to R4.2 billion, with a total of 8 632 employees across all levels, as detailed in Table 4.2. This personnel expenditure constitutes 36% of the NHLS' total expenditure.

Table 4.2: Personnel cost by salary band

Table 4.2: Personnel cost by salary band				
Programme/activity/objective	**Personnel Expenditure (R'000)**	**% of personnel exp. to total personnel cost (R'000)**	**No. of employees**	**Average personnel cost per employee (R'000)**
Top Management	15 479	0,37	7	2 211 336
Senior Management	105 294	2,51	50	2 106 883
Professional Qualified	1 102 846	26,24	944	1 168 269
Skilled	1 844 426	43,89	3288	560 957
Semi-skilled	961 219	22,87	3142	305 926
Unskilled	107 481	2,56	808	133 021
Training - learnerships	65 654	1,56	393	167 059
Total	**4 202 399**	**100%**	**8632**	**486 84**

The majority of the NHLS staff is found in the skilled occupational level, representing 43.9% of the total staff complement. The personnel expenditure is at R1.8 billion, which increased in comparison to the previous years (R1.7 billion). This is followed by the professionally qualified group, which represents 26% (R1.1 billion) of personnel costs, which also increased compared to the previous year's R1 billion. Training of students and interns, such as medical technicians, technologists, scientists and laboratory assistants, increased from 336 in the previous year to 393 (a difference of 57).

The personnel expenditure increased considerably in this financial year. This can be attributed to the COVID-19 pandemic, which resulted in the NHLS having to recruit and appoint more healthcare professionals to assist with testing and counselling, as well as general administration for the South African public in dealing with the pandemic, i.e. nurses, phlebotomy officers, drivers, medical technologists any many others.

There were no annual salary increases during this financial cycle, which could also have seen a higher rise in the total salary bill. The NHLS received a directive from the Minister of Health not to increase the salary bill without seeking permission. Although management engaged with labour on the annual wage negotiations, no agreement was signed pending approval of the Minister of Health.

Table 4.3: Cost per occupational category

Job Category	No. of employees	Personnel Expenditure (R'000)	% to total personnel cost (R'000)
Pathologist	234	418 107 767	10
Medical Scientist	253	181 441 46	4
Technologist	1720	953 204 332	23
Technician	802	377 840 103	9
Laboratory support	3721	1 621 306 556	39
Other support	1509	578 185 259	14
Training - learnerships	393	72 313 521	2
Total	**8632**	**4 202 399**	**100%**

Table 4.3 depicts that the four key medical roles constitute 46% (excluding students) of the total workforce at a personnel cost of R1.9 billion, with 38.58% being laboratory support at a cost of R1.6 billion. It is evident that the NHLS' total attrition is geared towards direct labour of core health professionals and laboratory support, which represents 85% of total staff.

Performance rewards

There was no payment of performance pay progressions during this financial cycle because of there being no annual wage negotiations agreement.

Table 4.4: Training costs

Training type	Personnel Expenditure R'000	Training Expenditure R'000	Training Expenditure as a % of Personnel Cost (%)	No. of Employees Trained	Average Training Cost per Employee (R)
Non-PIVOTAL* programmes (short courses, workshops, seminars, congresses and continuous professional development interventions)	4 202 399	15 257 578	0,0004	1919	3000
PIVOTAL programmes (Qualifications)		9 004 837		301	3000
PIVOTAL programmes for non-employees (higher education qualifications)	N/A	N/A	N/A	N/A	N/A
Learnerships, on-the-job training and work integrated learning	65 662 78	1 814 585	0,5512	393	

* PIVOTAL = Professional, vocational, technical and academic learning programmes that result in occupational qualifications or part qualifications on the National Qualifications Framework.

The NHLS continues to fulfil its role in promoting and prioritising skills development through the analysis of its employees' skills needs by implementing the Workplace Skills Plan (WSP). Multiple learning programmes are offered through short learning programmes, in-service conferences and congresses, as well as continuing professional development (CPD) programmes to enable the organisation to comply with legislation, improve the quality of services, ensure business continuity and assist in the mitigation of risks.

In the financial year under review, the NHLS achieved only 31% of the planned training target compared to the legislated target of 60%. This figure is represented by a training headcount of 2 220 employees who attended technical and non-technical short learning programmes, workshops, seminars, on-the-job training and conferences in 2020/21.

A total of 301 bursaries were issued to NHLS staff who wish to pursue their career development by way of formal qualifications. The NHLS had various training platforms, in which 393 personnel were trained. This includes medical technologist students, medical technician students, medical officers in community service, medical scientists and experiential students.

The non-compliance with statutory requirements for the financial year was due to the COVID-19 pandemic as there was a delay in adopting and implementing online training as the organisation adapted to the new COVID-19 environment and requirements. In the next financial year, the NHLS is planning to offer both face-to-face and online training to diversify its training delivery based on individual needs or line functions at all levels of the NHLS.

Table 4.5: Employment and vacancies

Programme/activity/ objective	2019/2020 No. of Employees	2019/2020	2020/2021	2020/2021 Vacancies	% of vacancies
		Approved Posts	No. of Employees		
Top Management	7	10	7	3	30
Senior Management	51	60	50	10	12.2
Professional Qualified	935	1233	944	289	25.1
Skilled	3036	3472	3288	184	5.7
Semi-skilled	2427	3336	3142	194	7.4
Unskilled	790	840	808	32	3.9
Training – learner-ships	283	394	393	1	0.3
Total	**7529**	**9345**	**8632**	**713**	**8.7%**

Table 4.5 reflects the staff headcount at the beginning and end of the period under review, including vacancies. The staff headcount increased by 14.7% to 8 632 (7 529 in 2019/20) from 1 April 2020 to 31 March 2021. This increase in the staff headcount is attributed to the recruitment and placement of health professionals and laboratory support staff required for COVID-19 posts in all the NHLS' national laboratories. The workforce planning framework at the beginning of the period under review did not anticipate such a high demand for health professionals and laboratory support personnel to be recruited in the 2020/21 financial year. The demand for health professionals and laboratory staff remained critical and on an upward curve during the course of the period under review. There is a global demand for health professionals due to the impact of the COVID-19 pandemic, which creates a limited pool of resources for health organisations to source the required skills timeously.

The vacancy rate of 8.7% reflects budgeted vacant positions at the end of the period under review, which is a little higher than the previous financial year. This is due to the strategic priority that arose due to the high demand of laboratory staff required to support the diagnostic services needed in response to the COVID-19 pandemic.

Table 4.6: Employment changes

Programme/activity/objective	Employment at beginning of period	Appointments	Terminations	Employment at end of the period
Top Management	7	1	1	7
Senior Management	51	3	4	50
Professional Qualified	935	121	76	951
Skilled	3036	457	166	3324
Semi-skilled	2427	882	197	3114
Unskilled	790	74	87	778
Training - learnerships	283	167	71	408
Total	**7529**	**1705**	**602**	**8632**

As shown in Table 4.6, appointments in the various occupational categories increased compared to the previous year, which can be attributed to the higher intake of health professionals and laboratory support staff in response to the impact of the COVID-19 pandemic. This was about 47% of total appointments. A high increase in staff appointments was mainly recorded in the skilled and semi-skilled job categories, as it is in these two categories that the majority of the NHLS' health professionals and laboratory support staff are recorded. Skilled staff increased by 9.5% compared to the previous year, while the semi-skilled category increased by 28% compared to 2019/20.

Total terminations processed during the period under review amounted to 1 204, while 50% of these terminations were rehired during the period to support the critical services required in the laboratories. Only 50% of the 1 204 total terminations exited the NHLS due to retirement, death, dismissal and ill health, as well as the expiry of contracts for non-core roles. Of the employees that exited the organisation, 38% were voluntary resignations.

Table 4.7: Reasons for leaving

Reason	Total Count	% of total no. of staff leaving
Death	35	0.4
Resignation	233	2.7
Dismissal	20	0.2
Retirement	72	0.8
Ill health	6	0.1
Expiry of contract	228	2.6
Other	8	0.1
Total	**602**	**7%**

Voluntary resignations in the current reporting period totalled 2.7% as a percentage of the total staff headcount, which equates to 38% of the total exits. The overall staff turnover rate, excluding end of contracts, was 4.4%, which is considered a very healthy turnover for any organisation. During the period under review, there was a slight drop in employees who left the organisation due to ill-health compared to the previous financial year. Another positive statistic was the dismissal of staff, which also decreased by 14% compared to the previous year. It is, however, with a heavy heart that we report that the number of deceased staff members doubled compared to last year. This could again be attributed to the impact of the COVID-19 pandemic.

Table 4.8: Labour relations – misconduct and disciplinary action

Nature of disciplinary Action	Number
Verbal Warning	14
Written Warning	12
Final Written warning	21
Dismissal	20
Not Guilty	15
Pending	19
Total	**101**

Table 4.8 shows the number of cases attended to and the outcomes.

Table 4.9a: Equity target and employment equity status – males per ethnic group

Programme/activity/ objective	Male							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top Management	2	3	0	1	0	0	1	1
Senior Management	8	12	1	1	2	3	7	8
Professional Qualified	122	126	28	29	45	45	88	88
Skilled	738	853	71	83	55	55	50	64
Semi-skilled	752	850	73	108	35	38	12	22
Unskilled	295	301	8	8	0	0	1	1
Total	**1917**	**2145**	**181**	**230**	**137**	**141**	**159**	**184**

African and coloured males are the most under-represented demographic group when compared to the economically active population demographics provided by the Department of Employment and Labour. The under-representation can be noted in the senior management, professionally qualified and skilled levels, thus making these groups the preferred targets. Indian and white males are the most over-represented demographic group. This can be noted in the senior and the professionally qualified levels.

Positive movements have been recorded in all the race and gender groups compared to the previous year. African males increased by 6.5% and coloured males by 7.1%; Indian males decreased by 4.3% and white males by 8.1%.

Table 4.9b: Equity target and employment equity status – females per ethnic group

Programme/activity/ objective	Female							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top Management	2	2	0	0	1	1	0	1
Senior Management	8	10	2	2	6	7	13	13
Professional Qualified	281	277	32	32	107	108	198	196
Skilled	1637	1817	170	174	175	174	225	235
Semi-skilled	1495	1410	199	199	45	50	64	69
Unskilled	455	460	23	21	1	1	0	0
Total	**3878**	**3976**	**426**	**428**	**335**	**341**	**500**	**514**

African females are mostly under-represented in senior management and the professionally qualified levels and remain the main target group. Coloured females are only under-represented in the professionally qualified level, while they align to the economically active population demographics in senior management. Indian and white females are over-represented in the senior and professionally qualified levels.

Positive movements were recorded in the following race and gender groups: African females increased by 7.3%, coloured females increased by 5.1%, Indian females decreased by 0.6% and white females decreased by 2.2%.

Table 4.9c: Equity target and employment equity status – people with disabilities

Programme/activity/objective	Disabled staff			
	Male		Female	
	Current	Target	Current	Target
Top Management	0	0	0	0
Senior Management	0	1	1	2
Professional Qualified	0	1	0	1
Skilled	2	2	19	20
Semi-skilled	3	2	5	7
Unskilled	2	3	3	4
Total	**7**	**9**	**28**	**34**

The representation of people living with disabilities remains at 0.5%, which is 1.5% below the compliance target of 2%. There have not been any changes in terms of movement.

PART E
FINANCIAL INFORMATION

General Information

Country of in corporation and domicile	SouthAfrica
Nature of business and principal activities	Health care, research and training
Board members	Prof Eric Buch Prof Jeffrey Mphahlele Dr Kamy Chetty Dr Lesley Bamford Mr Ben Durham Dr Gerhard Goosen Prof Mpho Klass Kgomo Mr Jonathan Mallett Prof Thanyani Mariba Dr Siseko Martin Dr Balekile Mzangwa Mr Koena Nkoko Dr Naledzani Ramalivhana Prof Mary Ross Mr Michael Sachs Mr Michael Shingange Mr Ian van der Merwe Mrs Nicolene van der Westhuizen
Registered office	1 Modderfontein Road Rietfontein Sandringham Johannesburg 2000
Postal address	Private Bag X8 Johannesburg 2131
Share holder	National Department of Health
Bankers	First National Bank Ltd Nedbank Ltd Investec Ltd Rand Merchant Bank Ltd
Auditors	NexiaSAB&T
Website	www.nhls.ac.za
Practice number	PR5200296
Legislation governing NHLS operations	The National Health Laboratory Service (NHLS) Act no.37 of 2000 The Public Finance Management (PFMA) Act, no. 1 of 1999 Treasury regulations in terms of PFMA,1999 The Companies Act No.71of 2008 The National Health Act, No.61 of 2003
Published	31 August 2021

Index

The reports and statements set out below comprise the audited annual financial statements presented to parliament:

Mr Jonas Shai
Acting CFO as from 1 January 2021

Chief Financial Officer's Report

Introduction

The 2020/21 financial year was characterised by activities that aimed to support the fight against the COVID-19 pandemic. To this end, there was a cannibalisation of cash reserves by upfront costs that were incurred to gear up the National Health Laboratory Service (NHLS) to be able to provide diagnostic services for the response to the COVID-19 pandemic.

Overview: Statement of Financial Performance

The NHLS generated a surplus of R54.3 million for the 2020/21 financial year, which is a decrease from R1.1 billion in the previous financial year. The organisation's revenue also grew from R9.3 billion to R10.7 billion. Revenue from rendering services accounts for 91% (R9.7 billion) of total revenue. Revenue pertaining to COVID-19 testing amounted to R1.9 billion, with over four million tests conducted.

Costs of sales, which includes direct labour and material, grew from R7.4 billion to R10.6 billion. This equates to a 43% increase, which was partly due to the acquisition of personal protective equipment, reagents and consumables in the response to the COVID-19 pandemic. Labour costs constituted 37% of the cost of sales. Direct material costs constituted 62% of the cost of sales, compared to 49% in the previous financial year.

Overview: Statement of Financial Position

The NHLS' assets increased from a restated R7.0 billion to R7.3 billion. Inventory increased in line with the additional procurement of masks, sanitisers, reagents and consumables. Receivables increased in line with revenue due to additional testing for the COVID-19 pandemic. Property, plant and equipment increased in line with additions to laboratory equipment, also as a consequence of gearing up for COVID-19 testing. Cash and cash equivalents decreased from R4.1 billion to R3 billion in the current year. Current liabilities increased from R1.7 billion to R1.9 billion (a 12% increase) due to an increase in payables from exchange transactions. The NHLS has maintained strong financial viability, even after taking the significant reduction in cash reserves into account.

Cash flow

A net cash outflow of R1.1 billion was incurred in the 2020/21 financial year. This is mainly attributable to a net cash outflow from operating activities of R738 million. Suppliers were paid R7.7 billion during the year compared with only R4.6 billion in the prior year. Employee costs amounted to R4.2 billion. A net cash outflow from investing activities of R389 million was also incurred. This is mainly attributable to the purchase of laboratory equipment. An amount of R251 million was also received from the Solidarity Fund during the financial year to respond to the COVID-19 pandemic.

Going concern

Given its significance in the public and private health sectors and its ability to deliver affordable pathology health services to the South African public, the Department of Health has neither the intention nor the need to liquidate or curtail the scale of the NHLS. Management considered a wide range of factors in determining whether the organisation is a going concern. These factors include its current and expected performance as a Schedule 3A public entity, its restructuring plans and the likelihood of future government funding. For the financial period under review, the NHLS has maintained cash and cash equivalents at

levels that ensure continuity of service. Debtors' collection remains within acceptable levels. The group's annual financial statements were therefore prepared based on the accounting policies applicable to a going concern.

In line with the applicable accounting standards, this basis presumes that funds will be available to finance future operations and that the realisation of assets and liabilities, contingent obligations and commitments will occur in the ordinary course of business. This specifically assumes that the debt owed by provinces will continue to be serviced.

Maintenance of financial control systems

The Board is ultimately responsible for systems of internal financial control within the NHLS and places considerable importance on maintaining a strong control environment. Based on assessments of internal and external audits, assurance is provided that the NHLS' internal controls are effective. Without qualifying the effectiveness of controls, internal and external audit has also highlighted the need to strengthen controls pertaining to procurement and contract management.

Borrowing limitations

In terms of the NHLS' rules, the Board may exercise all the powers of the economic entity to borrow money as it considers appropriate, in accordance with the PFMA. During the financial year under review, the entity did not borrow funds to finance its operations.

Acknowledgements

It is imperative to express appreciation to the Board for the strategic direction provided during a very difficult year in our country's democratic history and that of the NHLS. The leadership of the CEO has proven to be invaluable in carrying out the entity's mandate. The dedication of the NHLS' management and staff has brought to bear the true spirit of service. May the spirit of colleagues and family members that we have lost in the past year find peace in the continuous efforts of the NHLS in contributing to a healthier South Africa.

Mr Jonas Shai

Acting CFO

Accounting Authority's Responsibilities and Approval

The Accounting Authority is required by the Public Finance Management Act (Act 1 of 1999), to maintain adequate accounting records and is responsible for the content and integrity of the group Annual Financial Statements and related financial information included in this report. It is the responsibility of the Accounting Authority to ensure that the group Annual Financial Statements fairly present the state of affairs of the economic entity as at the end of the financial year and the results of its operations and cash flows for the year then ended. The external auditors are engaged to express an independent opinion on the audited annual financial statements and was given unrestricted access to all financial records and related data.

The group Annual Financial Statement have been prepared in accordance with Standards of Generally Recognised Accounting Practice (GRAP) including any interpretations, guidelines and directives issued by the Accounting Standards Board.

The audited group Annual Financial Statement are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The Accounting Authority acknowledges that is ultimately responsible for the system of internal financial control established by the economic entity and place considerable importance on maintaining a strong control environment. To enable the Accounting Authority to meet these responsibilities, the Accounting Authority sets standards for internal control aimed at reducing the risk of error or deficit in a cost effective manner. The standards include the proper delegation of responsibilities within a clearly defined framework, effective accounting procedures and adequate segregation of duties to ensure an acceptable level of risk. These controls are monitored through out the economic entity and all employees are required to maintain the highest ethical standards in ensuring the economic entity's business is conducted in a manner that in all reasonable circumstances is above reproach.The focus of risk management in the economic entity is on identifying, assessing, managing and monitoring all known forms of risk across the economic entity. While operating risk cannot be fully eliminated, the economic entity endeavours to minimise it by ensuring that appropriate infrastructure, controls, systems and ethical behaviour are applied and managed within predetermined procedures and constraints.

The Accounting Authority is of the opinion, based on the information and explanations given by management, that the system of internal control provides reasonable assurance that the financial records may be relied on for the preparation of the audited annual financial statements. However, any system of internal financial control can provide only reasonable, and not absolute, assurance against material misstatement or error.

The Accounting Authority has reviewed the economic entity's cash flow forecast and, in the light of this review and the current financial position, he is satisfied that the foreseeable future economic entity has access to adequate resources to continue in operational existence for thefore see able future.

The economic entity is wholly dependent on public health care providers for continued funding of operations. The audited annual financial statements are prepared on the basis that the economicentity is a going concern and that the National Department of Health has neither the intention nor the need to liquidate or curtail materially the scale of the economic entity.

Although the Accounting authority is primarily responsible for the financial affairs of the economic entity, it is supported by the economic entity's internal auditors.

The audited annual financial statements set out on pages 158 to 230 which have been prepared on the going concern basis, where approved by the Accounting Authority on 05 August 2021 and were signed on its behalf by:

Prof Eric Buch

Chaiperson: Accounting Authority

Dr Kamy Chetty

Chief Executive Officer

Independent Auditor's report to Parliament on National Health Laboratory Service

Report on the audit of the consolidated and separate financial statements

Opinion

1. We have audited the consolidated and separate financial statements of the National Health Laboratory Service and the subsidiary (the group) set out on pages 158 to 230, which comprise the consolidated and separate statement of financial position as at 31 March 2021, the consolidated and separate statement of financial performance, statement of changes in net assets, cash flow statement and Statement of Comparison of Budget and Actual Amounts for the year then ended, as well as notes to the consolidated and separate financial statements, including a summary of significant accounting policies.

2. In our opinion, the consolidated and separate financial statements present fairly, in all material respects, the financial position of the group as at 31 March 2021, and their financial performance and cash flows for the year then ended in accordance with South African Standards of Generally Recognised Accounting Practice (SA Standards of GRAP) and the requirements of the Public Finance Management Act of South Africa, 1999 (Act No. 1 of 1999) (PFMA).

Basis for opinion

3. We conducted our audit in accordance with the International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the auditor's responsibilities for the audit of the consolidated and separate financial statements section of our report.

4. We are independent of the group in accordance with Independent Regulatory Board for Auditors' *Code of Professional Conduct for Auditors* (IRBA Code) and other independence requirements applicable to performing audits of financial statements in South Africa. We have fulfilled our other ethical responsibilities in accordance with the IRBA Code and in accordance with other ethical requirements applicable to performing audits in South Africa. The IRBA Code is consistent with the corresponding sections of the International Ethics Standards Board for Accountants' *International Code of Ethics for Professional Accountants (Including International Independence Standards).*

5. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of matter

6. We draw attention to the matters below. Our opinion is not modified in respect of these matters.

Restatement of corresponding figures

7. As disclosed in note 38 to the financial statements, the corresponding figures for 31 March 2020 were restated as a result of an error in the financial statements of the entity at, and for the year ended, 31 March 2021.

Material allowance for impairment

8. As disclosed in note 4 to the financial statements, material allowance for impairment of R3 805 975 000 was recorded against receivables from exchange transactions as a result of irrecoverable debt.

Irregular expenditure

9. As disclosed in note 37 to the financial statements, the entity incurred irregular expenditure of R778 639 000 (2020: R776 388 000). There are further matters under assessment and investigation, which may result in additional irregular expenditure but the nature and extent of which have not been established at reporting date.

Other matter

10. We draw attention to the matter below. Our opinion is not modified in respect of this matter.

Unaudited supplementary information

11. The supplementary information set out on pages 231 to 233 does not form part of the financial statements and is presented as additional information. We have not audited this schedule and, accordingly, we do not express an opinion on it.

Responsibilities of accounting authority for the financial statements

12. The board of directors, which constitutes the accounting authority, is responsible for the preparation and fair presentation of the consolidated and separate financial statements in accordance with SA Standards of GRAP and the requirements of the PFMA, and for such internal control as the accounting authority determines is necessary to enable the preparation of consolidated and separate financial statements that are free from material misstatement, whether due to fraud or error.

13. In preparing the consolidated and separate financial statements, the accounting authority is responsible for assessing the group's ability to continue as a going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting unless the accounting authority either intends to liquidate the group or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the consolidated and separate financial statements

14. Our objectives are to obtain reasonable assurance about whether the consolidated and separate financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated and separate financial statements.

15. A further description of our responsibilities for the audit of the consolidated and separate financial statements is included in the annexure to this auditor's report.

Report on the audit of the annual performance report

Introduction and scope

16. In accordance with the Public Audit Act 25 of 2004 (PAA) and the general notice issued in terms thereof, we have a responsibility to report on the usefulness and reliability of the reported performance information against predetermined objectives for selected programme presented in the annual performance report. We performed procedures to identify material findings but not to gather evidence to express assurance.

17. Our procedures address the usefulness and reliability of the reported performance information, which must be based on the group's approved performance planning documents. We have not evaluated the completeness and appropriateness of the performance indicators included in the planning documents. Our procedures do not examine whether the actions taken by the group enabled service delivery. Our procedures do not extend to any disclosures or assertions relating to the extent of achievements in the current year or planned performance strategies and information in respect of future periods that may be included as part of the reported performance information. Accordingly, our findings do not extend to these matters.

18. We evaluated the usefulness and reliability of the reported performance information in accordance with the criteria developed from the performance management and reporting framework, as defined in the general notice, for the following selected programme presented in the group's annual performance report for the year ended 31 March 2021:

Programme	Pages in the annual performance report
Programme 1 – Laboratory Service	31 to 42

19. We performed procedures to determine whether the reported performance information was properly presented and whether performance was consistent with the approved performance planning documents. We performed further procedures to determine whether the indicators and related targets were measurable and relevant, and assessed the reliability of the reported performance information to determine whether it was valid, accurate and complete.

20. We did not identify any material findings on the usefulness and reliability of the reported performance information for this programme.

Other matter

21. We draw attention to the matter below.

Achievement of planned targets

22. Refer to the annual performance report on pages 31 to 42 for information on the achievement of planned targets for the year and management's explanations provided for the under/over achievement of targets.

Report on the audit of compliance with legislation

Introduction and scope

23. In accordance with the PAA and the general notice issued in terms thereof, we have a responsibility to report material findings on the group's compliance with specific matters in key legislation. We performed procedures to identify findings but not to gather evidence to express assurance.

24. The material findings on compliance with specific matters in key legislation are as follows:

Annual financial statements

25. The financial statements submitted for auditing were not prepared in accordance with the prescribed financial reporting framework, as required by section 55(1) (b) of the PFMA.

26. Material misstatements of revenue, non-current assets, current assets, liabilities and disclosure items identified by the auditors in the submitted financial statement were corrected, resulting in the financial statements receiving an unqualified audit opinion.

Expenditure management

27. Effective and appropriate steps were not taken to prevent irregular expenditure amounting to R778 639 000 as disclosed in note 37 to the annual financial statements, as required by section 51(1)(b)(ii) of the PFMA. The majority of the irregular expenditure incurred was caused by non-compliance with laws and regulations governing procurement and contract management.

Procurement and contract management

28. Some of the quotations and contracts were accepted from prospective suppliers who did not submit a declaration on whether they are employed by the state or connected to any person employed by the state, as required by Treasury Regulation 16A8.4 and paragraph 4.1.2 of Practice Note 7 of 2009/2010.

29. Some of the quotations were awarded to suppliers whose tax matters had not been declared by the South African Revenue Services to be in order as required by Treasury Regulation 16A9.1(d).

30. In some instances the prices of Personal Protective Equipment items charged by suppliers were not in accordance with Annexure A of the National Treasury Instruction note 8 of 2020/21 as required by paragraph 3.1.1 of the same instruction note.

Other information

31. The accounting authority is responsible for the other information. The other information comprises the information included in the annual report, which includes Foreword by the Chairperson of the Board, Chief Executive Officer's Overview, Chief Financial Officer's Report, Accounting Authority's Responsibility and Approval and Report of the Audit and Risk Committee. The other information does not include the consolidated and separate financial statements, the auditor's report and those selected programme presented in the annual performance report that have been specifically reported in this auditor's report.

32. Our opinion on the financial statements and our findings on the reported performance information and compliance with legislation do not cover the other information and we do not express an audit opinion or any form of assurance conclusion on it.

33. In connection with our audit, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated and separate financial statements and the selected programme presented in the annual performance report, or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

34. If based on the work we have performed, we conclude that there is a material misstatement in this other information, we are required to report that fact. We have nothing to report in this regard.

Internal control deficiencies

35. We considered internal control relevant to our audit of the consolidated and separate financial statements, reported performance information and compliance with applicable legislation; however, our objective was not to express any form of assurance on it. The matter reported below is limited to the significant internal control deficiencies that resulted in the findings on compliance with legislation included in this report.

36. Management did not implement effective controls to ensure accurate financial reporting, nor did they exercise adequate oversight responsibility over compliance with applicable legislation, which resulted in irregular expenditure and material adjustments made to the financial statements.

Other reports

37. We draw attention to the following engagements conducted by various parties which had, or could have, an impact on the matters reported in the group's financial statements, reported performance information, compliance with applicable legislation and other related matters. These reports did not form part of our opinion on the financial statements or our findings on the reported performance information or compliance with legislation.

38. The Special Investigations Unit is currently investigating allegations of the possible procurement and contract management irregularities at the request of the President of the Republic of South Africa (Proclamation No R.18 of 2019), covering the period 2016 to 2017. The investigations were still in progress at the date of this auditor's report.

39. The Directorate for Priority Crime Investigation ("The Hawks") is currently investigating allegations of the possible procurement and contract management irregularities. The investigations were still in progress at the date of this auditor's report.

40. An independent consultant is currently conducting a forensic investigation in respect of allegations pertaining to purchase orders awarded to some companies relating to the Covid-19 emergency procurement events at the request of the entity. These proceedings were in progress at the date of this auditor's report.

Auditor tenure

41. In terms of the IRBA rule published in *Government gazette number 39475* dated 4 December 2015, we report that Nexia SAB&T has been the auditor of National Health Laboratory Service for 2 years.

Nexia SAB&T

Nexia SAB&T
N.C Soopal
Director
Registered Auditor

31 August 2021

119 Witch Hazel Avenue
Highveld Technopark
Centurion
0146

Annexure – Auditor-general's responsibility for the audit

1. As part of an audit in accordance with the ISAs, I exercise professional judgement and maintain professional scepticism throughout my audit of the financial statements and the procedures performed on reported performance information for selected programmes and on the public entity's compliance with respect to the selected subject matters.

Financial statements

2. In addition to my responsibility for the audit of the financial statements as described in this auditor's report, I also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error; design and perform audit procedures responsive to those risks; and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal control
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the public entity's internal control
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the accounting authority
- conclude on the appropriateness of the accounting authority's use of the going concern basis of accounting in the preparation of the financial statements. I also conclude, based on the audit evidence obtained, whether a material uncertainty exists relating to events or conditions that may cast significant doubt on the ability of the Mining Qualifications Authority to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements about the material uncertainty or, if such disclosures are inadequate, to modify my opinion on the financial statements. My conclusions are based on the information available to me at the date of this auditor's report. However, future events or conditions may cause a public entity to cease operating as a going concern
- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and determine whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Communication with those charged with governance

3. I communicate with the accounting authority regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

Statement of Financial Position as at 31 March 2021

		Economic entity		Controlling entity	
	Note(s)	2021	2020 Restated*	2021	2020 Restated*
Assets					
Current Assets					
Inventories	3	1 120 828	166 122	1 115 882	160 302
Receivables from exchange transactions	4	1 443 164	1 265 678	1 440 514	1 263 716
Receivables from non-exchange transactions	5	414 474	450 245	414 474	450 245
Cash and cash equivalents	6	2 952 072	4 105 760	2 942 959	4 094 633
		5 930 538	**5 987 805**	**5 913 829**	**5 968 896**
Non-Current Assets					
Property plant and equipment	7	1 330 849	1 048 202	1 328 891	1 046 456
Intangible assets	8	6 506	4 799	6 506	4 799
		1 337 355	**1 053 001**	**1 335 397**	**1 051 255**
Total Assets		**7 267 893**	**7 040 806**	**7 249 226**	**7 020 151**
Liabilities					
Current Liabilities					
Other financial liabilities	11	4 920	4 824	4 920	4 824
Current tax payable		2 026	1 693	-	-
Finance lease obligation	12	18 727	18 148	18 727	18 148
Payables from exchange transactions	13	1 140 40	725 876	1 139 133	723 277
VAT payable		108	165	-	-
Post retirement medical benefit plan	14	37 510	34 905	37 510	34 905
Unspent conditional grants and receipts	15	17 548	35 581	17 548	35 581
Provisions	16	674 754	841 392	674 754	841 392
		1 895 765	**1 662 584**	**1 892 592**	**1 658 127**
Non-Current Liabilities					
Other financial liabilities	11	-	5 056	-	5 056
Finance lease obligation	12	102	18 982	102	18 982
Post retirement medical benefit plan	14	881 878	918 492	881 878	918 492
Deferred tax	17	389	242	-	-
		882 369	**942 772**	**881 980**	**942 530**
Total Liabilities		**2 778 134**	**2 605 356**	**2 774 572**	**2 600 657**
Net Assets		**4 489 759**	**4 435 450**	**4 474 654**	**4 419 494**
Reserves					
Revaluation reserve		654 919	654 919	654 919	654 919
Accumulated surplus		3 834 840	3 780 531	3 819 735	3 764 575
Total Net Assets		**4 489 759**	**4 435 450**	**4 474 654**	**4 419 494**

* See note 38

Statement of Financial Performance

		Economic entity		Controlling entity	
	Note(s)	2021	2020 Restated*	2021	2020 Restated*
Revenue	18	10 676 573	9 250 665	10 650 931	9 221 548
Cost of sales	19	(10 571 881)	(7 365 003)	(10 549 259)	(7 339 549)
Gross surplus		**104 692**	**1 885 662**	**101 672**	**1 881 999**
Other income	20	1 022 924	180 681	1 022 924	180 680
Operating expenses	26	(1 232 850)	(1 300 432)	(1 228 925)	(1 296 253)
Operating (deficit) surplus	21	**(105 234)**	**765 911**	**(104 329)**	**766 426**
Interest income	22	163 705	315 841	163 186	315 212
Fair value adjustments		15	(23)	-	-
Interest expense	23	(3 697)	(6 278)	(3 697)	(6 153)
Surplus before taxation		**54 789**	**1 075 451**	**55 160**	**1 075 485**
Taxation	24	(480)	(816)	-	-
Surplus for the years		**54 309**	**1 074 635**	**55 160**	**1 075 485**

* See note 38

Statement of Changes in Net Assets

	Share capital / contributed capital	Revaluation reserve	Accumulated surplus	Total net assets
	R'000	R'000	R'000	R'000
Economic entity				
Opening balance as previously reported	332	654 919	2 667 775	3 323 026
Adjustments				
Correction of errors	(332)	-	38 121	37 789
Balance at 01 April 2019 as restated	**-**	**654 919**	**2 705 896**	**3 360 815**
Changes in net assets				
Surplus for the year	-	-	1 074 635	1 074 635
Total changes	-	-	1 074 635	1 074 635
Opening balance as previously reported	332	654 919	3 749 997	4 405 248
Adjustments				
Correction of errors	(332)	-	30 534	30 202
Restated* Balance at 01 April 2020	**-**	**654 919**	**3 780 531**	**4 435 450**
Changes in net assets				
Surplus for the year	-	-	54 309	54 309
Total changes	-	-	54 309	54 309
Balance at 31 March 2021		**654 919**	**3 834 840**	**4 489 759**
Controlling entity				
Opening balance as previously reported Adjustments	332	654 919	2 652 607	3 307 858
Correction of errors	(332)	-	36 483	36 151
Balance at 01 April 2019 as restated	**-**	**654 919**	**2 689 090**	**3 344 009**
Changes in net assets				
Surplus for the year	-	-	1 075 485	1 075 485
Total changes			1 075 485	1 075 485
Opening balance as previously reported	-	654 919	3 735 547	4 390 466
Adjustments				
Correction of errors	-	-	29 028	29 028
Restated* Balance at 01 April 2020	**-**	**654 919**	**3 764 575**	**4 419 494**
Changes in net assets				
Surplus for the year	-	-	55 160	55 160
Total changes	-	-	55 160	55 160
Balance at 31 March 2021	**-**	**654 919**	**3 819 735**	**4 474 654**

* See note 38

Cash Flow Statement

	Note(s)	Economic entity		Controlling entity	
		2021	2020 Restated*	2021	2020 Restated*
		R'000	R'000	R'000	R'000
Cash flows from operating activities					
Receipts					
Sale of goods and services		10 158 807	9 433 705	10 133 853	9 404 075
Grants		855 584	785 506	855 584	785 506
Interest income		165 774	313 899	165 255	313 270
		11 180 165	10 533 110	11 154 692	10 502 851
Payments					
Employee costs		(4 171 445)	(3 938 110)	(4 155 344)	(3 922 283)
Suppliers		(7 746 792)	(4 555 280)	(7 735 406)	(4 546 804)
Interest expense		(16)	(136)	(16)	(11)
Taxes on surpluses	30	-	(801)	-	-
		(11 918 253)	(8 494 327)	(11 890 766)	(8 469 098)
Net cash flows from operating activities	29	**(738 088)**	**2 038 783**	**(736 074)**	**2 033 753**
Cash flows from investing activities					
Purchase of property, plant and equipment	7	(386 042)	(109 327)	(386 042)	(109 068)
Proceeds from sale of property plant and equipment	7	-	886	-	886
Purchase of intangible asset	8	(2 616)	(4 479)	(2 616)	(4 479)
Net cash flows from investing activities		**(388 658)**	**(112 920)**	**(388 658)**	**(112 661)**
Cash flows from financing activities					
Repayment of other financial liabilities		(4 960)	(4 060)	(4 960)	(4 060)
Finance lease payments		(21 982)	(24 136)	(21 982)	(24 136)
Net cash flows from financing activities		**(26 942)**	**(28 196)**	**(26 942)**	**(28 196)**
Net increase in cash and cash equivalents		**(1 153 688)**	**1 897 667**	**(1 151 674)**	**1 892 896**
Cash and cash equivalents at the beginning of the year		4 105 760	2 208 093	4 094 633	2 201 737
Cash and cash equivalents at the end of the year	6	**2 952 072**	**4 105 760**	**2 942 959**	**4 094 633**

* See note 38

Statement of Comparison of Budget and Actual Amounts

Budget on Accrual Basis

	Approved budget	Adjustments	Final Budget	Actual amounts on comparable basis	Difference between final budget and actual	Reference
	R'000	R'000	R'000	R'000	R'000	
Economic entity						
Statement of Financial Performance						
Revenue						
Revenue from exchange transactions						
Sale of goods	35 785	**35 785**		25 642	**(10 143)**	
Rendering of services	8 744 448	**8 744 448**		9 752 964	**1 008 516**	43.1
Miscellaneous other revenue	8 800	**8 800**		42 383	**33 583**	
Fees earned	4 513	**4 513**		2 284	**(2 229)**	
Royalties received	458	**458**		2 063	**1 605**	
Bad debts recovered	1 003	**1 003**		305	**(698)**	
Internal Recoveries	7 554	**7 554**		502 922	**495 368**	43.2
Teaching Income	58 463	**58 463**		87 532	**29 069**	
Sundry income	12 793	**12 793**		826	**(11 967)**	
Grant income recognised				176 123	**176 123**	43.3
Public Contributions and Donations				250 869	**250 869**	43.4
Interest received	246 856	**246 856**		163 705	**(83 151)**	
Total revenue from exchange transactions	**9 120 673**	**9 120 673**		**11 007 618**	**1 886 945**	
Revenue from non-exchange transactions						
Transfer revenue						
Government grants & subsidies	747 455	**747 455**		855 584	**108 129**	
Total revenue	**9 868 128**	**9 868 128**		**11 863 202**	**1 995 074**	
Expenditure						
Personnel	(4 560 349)	**(4 560 349)**		(4 202 399)	**357 950**	
Depreciation and amortisation	(165 451)	**(165 451)**		(101 575)	**63 876**	
Finance costs	(5 878)	**(5 878)**		(3 697)	**2 181**	
Lease rentals on operating lease	(40 671)	**(40 671)**		(41 000)	**(329)**	
Debt Impairment	(73 788)	**(73 788)**		(32 654)	**41 134**	
General Expenses	(4 812 374)	**(4 812 374)**		(7 422 421)	**(2 610 047)**	43.5
Total expenditure	**(9 658 511)**	**(9 658 511)**		**(11 802 966)**	**(2 144 455)**	
Operating surplus	**209 617**	**209 617**		**60 236**	**(149 381)**	
Loss on disposal of assets and liabilities	(2)	**(2)**		(3 335)	**(3 333)**	
Loss on foreign exchange				(2 127)	**(2 127)**	
Fair value adjustments				15	**15**	
	(2)	**(2)**		**(5 447)**	**(5 445)**	
Surplus before taxation	**209 615**	**209 615**		**54 789**	**(154 826)**	
Taxation				480	**480**	
Actual Amount on Comparable Basis as Presented in the Budget and Actual Comparative Statement	**209 615**	**209 615**		**54 309**	**(155 306)**	

Accounting policies

1. Presentation of Audited Annual Financial Statement

The audited annual financial statements have been prepared in accordance with the Standards of Generally Recognised Accounting Practice (GRAP), issued by the Accounting Standards Board in accordance with Section 91(1) of the Public Finance Management Act (Act 1 of 1999).

These audited annual financial statements have been prepared on an accrual basis of accounting and are in accordance with historical cost convention as the basis of measurement, unless specified otherwise.

A summary of the significant accounting policies, which have been consistently applied in the preparation of these audited annual financial statements, are disclosed below.

These accounting policies are consistent with the previous period, except for the changes set out in the Changes in accounting policy note.

1.1 Presentation currency

These audited annual financial statements are presented in South African Rand, which is the functional currency of the economic entity and all values are rounded to the nearest thousand (R000), except when otherwise indicated.

1.2 Going concern assumption

These audited annual financial statements have been prepared based on the expectation that the economic entity will continue to operate as a going concern for at least the next 12 months.

1.3 Significant judgements and sources of estimation uncertainty

In preparing the audited annual financial statements, management is required to make estimates and assumptions that affect the amounts represented in the audited annual financial statements and related disclosures. Use of available information and the application of judgement is inherent in the formation of estimates. Actual results in the future could differ from these estimates which may be material to the audited annual financial statements. Significant judgements include:

Trade and other receivables

The economic entity assesses its trade and other receivables for impairment at the end of each reporting period. In determining whether an impairment loss should be recorded in surplus or deficit, the economic entity makes judgements as to whether there is observable data indicating a measurable decrease in the estimated future cash flows from a financial asset.

The impairment for trade and other receivables is calculated on a individual basis for major customers (others are grouped on a portfolio basis), based on historical loss ratios, adjusted for national and industry-specific economic conditions and other indicators present at the reporting date that correlate with defaults on the customer. These annual loss ratios are applied to loan balance of the customer or the portfolio and scaled to the estimated loss emergence period.

The impairment is measured as the difference between the debtors carrying amount and the present value of estimated future cash flows discounted at the effective interest rate, computed at initial recognition.

Allowance for slow moving damaged and obsolete stock

An allowance is raised to write stock down to the lower of cost or net realisable value. Management have made estimates of the selling price and direct cost to sell on certain inventory items.

Accounting policies

Impairment testing

The recoverable amounts of cash-generating units and individual assets are determined based on the higher of value-in-use calculations and fair values less costs to sell. These calculations require the use of estimates and assumptions. It is reasonably possible that the key assumptions may change which may then impact our estimations and may then require a material adjustment to the carrying value of tangible assets.

1.3 Significant judgements and sources of estimation uncertainty (continued)

The economic entity reviews and tests the carrying value of assets when events or changes in circumstances suggest that the carrying amount may not be recoverable. Assets are grouped at the lowest level for which identifiable cash flows are largely independent of cash flows of other assets and liabilities. If there are indications that impairment may have occurred, estimates are prepared of expected future cash flows for each group of assets. Expected future cash flows used to determine the value in use of tangible assets are inherently uncertain and could materially change over time. They are significantly affected by a number of factors including including production estimates, together with economic factors such as exchange rates, inflation rates and interest rates.

Provisions

Provisions were raised and management determined an estimate based on the information available. Additional disclosure of these estimates of provisions are included in note 16 - Provisions.

Useful lives of property plant and equipment

The economic entity's management determines the estimated useful lives and related depreciation charges for property, plant and equipment. This estimate is based on industry norm. Management will increase the depreciation charge where useful lives are less than previously estimated useful lives.

Post-retirement benefits

The present value of the post retirement obligation depends on a number of factors that are determined on an actuarial basis using a number of assumptions. The assumptions used in determining the net cost (income) include the discount rate, healthcare cost inflation, expected retirement age and withdrawal rate. Any changes in these assumptions will impact on the carrying amount of post retirement obligations.

The economic entity determines the appropriate discount rate at the end of each year. This is the interest rate that should be used to determine the present value of estimated future cash outflows expected to be required to settle the medical obligations. In determining the appropriate discount rate, the economic entity considers the interest rates of high-quality government bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating the terms of the related medical liability.

Other key assumptions for medical obligations are based on current market conditions. Additional information is disclosed in Note 14.

Accounting policies

1.4 Property plant and equipment

Property plant and equipment are tangible non-current assets (including infrastructure assets) that are held for use in the production or supply of goods or services, rental to others, or for administrative purposes, and are expected to be used during more than one period.

The cost of an item of property, plant and equipment is recognised as an asset when:

- it is probable that future economic benefits or service potential associated with the item will flow to the economic ntity; and
- the cost of the item can be measured reliably. Property, plant and equipment is initially measured at cost.

The cost of an item of property plant and equipment is the purchase price and other costs attributable to bring the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Trade discounts and rebates are deducted in arriving at the cost.

Where an asset is acquired through a non-exchange transaction, its cost is its fair value as at date of acquisition.

When significant components of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

Costs include costs incurred initially to acquire an item of property plant and equipment and costs incurred subsequently to add to, replace part of, or service it. If a replacement cost is recognised in the carrying amount of an item of property, plant and equipment, the carrying amount of the replaced part is derecognised.

Recognition of costs in the carrying amount of an item of property plant and equipment ceases when the item is in the location and condition necessary for it to be capable of operating in the manner intended by management.

Items such as spare parts, standby equipment and servicing equipment are recognised when they meet the definition of property, plant and equipment.

Major inspection costs which are a condition of continuing use of an item of property, plant and equipment and which meet the recognition criteria above are included as a replacement in the cost of the item of property plant and equipment. Any remaining inspection costs from the previous inspection are derecognised.

Property plant and equipment is subsequently carried at cost less accumulated depreciation and any impairment losses except for land and buildings plus sheep and horses. Buildings are carried at revalued amount being the fair value at the date of revaluation less any subsequent accumulated depreciation and subsequent accumulated impairment losses. Land is not depreciated but carried at revalued amount less accumulated impairment losses. Sheep and horses are held at fair value.
Revaluations are made with sufficient regularity such that the carrying amount does not differ materially from that which would be determined using fair value at the end of the reporting period.

When an item of property plant and equipment is revalued, any accumulated depreciation at the date of the revaluation is eliminated against the gross carrying amount of the asset and the net amount restated to the revalued amount of the asset.

Any increase in an asset's carrying amount, as a result of a revaluation, is credited directly to a revaluation surplus. The increase is recognised in surplus or deficit to the extent that it reverses a revaluation decrease of the same asset previously recognised in surplus or deficit.

Any decrease in an asset's carrying amount, as a result of a revaluation, is recognised in urplu or deficit in the current period. The decrease is debited directly to a revaluation surplus to the extent of any credit balance existing in the revaluation surplus in respect of that asset.

The revaluation surplus in equity related to a specific item of property plant and equipment is transferred directly to retained earnings when the asset is derecognised.

Accounting policies

1.4 Property plant and equipment (continued)

Property plant and equipment are depreciated on the straight line basis over their expected useful lives to their estimated residual value.

Sheep and horses that are used for research purposes are initially measured at cost and subsequently carried at cost less any accumulated depreciation and any accumulated impairment losses.

The useful lives of items of property, plant and equipment have been assessed as follows:

Item	Depreciation method	Average useful life
Buildings	Straight line	30 - 52 years
Laboratory equipment	Straight line	4 - 10 years
Plant and machinery	Straight lin	5 year
Furniture and fixtures	Straight line	10 – 20 years
Motor vehicles	Straight line	5 years
Office equipment	Straight line	3 – 10 years
Computer equipment	Straight line	3 - 5 years
Leasehold improvements	Straight line	5 - 8 years
Mobile units	Straight line	6 – 10 years
Buildings - air systems	Straight line	5 years

The depreciable amount of an asset is allocated on a systematic basis over its useful life.

Each part of an item of property, plant and equipment with a cost that is significant in relation to the total cost of the item is depreciated separately.

The depreciation method used reflects the pattern in which the asset's future economic benefits or service potential are expected to be consumed by the economic entity. The depreciation method applied to an asset is reviewed at least at each reporting date and, if there has been a significant change in the expected pattern of consumption of the future economic benefits or service potential embodied in the asset, the method is changed to reflect the changed pattern. Such a change is accounted for as a change in an accounting estimate.

Items of property plant and equipment are derecognised when the asset is disposed of or when there are no further economic benefits or service potential expected from the use of the asset.

The gain or loss arising from the derecognition of an item of property, plant and equipment is included in surplus or deficit when the item is derecognised. The gain or loss arising from the derecognition of an item of property plant and equipment is determined as the difference between the net disposal proceeds, if any, and the carrying amount of the item.

The economic entity separately discloses expenditure to repair and maintain property, plant and equipment in the notes to the financial statements (see note 8).

Accounting policies

1.5 Intangible assets

An intangible asset is identifiable if it either:

- is separable, i.e. is capable of being separated or divided from an entity and sold, transferred, licensed, rented or exchanged, either individually or together with a related contract, identifiable assets or liability, regardless of whether the entity intends to do so; or
- arises from binding arrangements (including rights from contracts), regardless of whether those rights are transferable or separable from the economic entity or from other rights and obligations.

A binding arrangement describes an arrangement that confers similar rights and obligations on the parties to it as if it were in the form of a contract.

An intangible asset is recognised when:

- it is probable that the expected future economic benefits or service potential that are attributable to the asset will flow to the economic entity; and
- the cost or fair value of the asset can be measured reliably.

The economic entity assesses the probability of expected future economic benefits or service potential using reasonable and supportable assumptions that represent management's best estimate of the set of economic conditions that will exist over the useful life of the asset.

Where an intangible asset is acquired through a non-exchange transaction, its initial cost at the date of acquisition is measured at its fair value as at that date.

Intangible assets are carried at cost less any accumulated amortisation and any impairment losses.

The amortisation period and the amortisation method for intangible assets are reviewed at each reporting date. Amortisation is provided to write down the intangible assets, on a straight line basis, to their residual values as follows:

Item	Depreciation method	Average useful life
Patent	Straight lin	20 year
Computer software	Straight line	5 - 10 years

Intangible assets are derecognised:

- on disposal; or
- when no future economic benefits or service potential are expected from its use or disposal.

The gain or loss arising from the derecognition of intangible assets is included in surplus or deficit when the asset is derecognised.

Accounting policies

1.6 Investments in controlled entities

Economic entity audited annual financial statements

Investment in controlled entities is consolidated in the economic entity audited annual financial statements.

Controlling entity audited annual financial statements

In the entity's separate audited annual financial statements, investments in controlled entities are carried at cost.

1.7 Financial instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or a residual interest of another entity.

The amortised cost of a financial asset or financial liability is the amount at which the financial asset or financial liability is measured at initial recognition minus principal repayments, plus or minus the cumulative amortisation using the effective interest method of any difference between that initial amount and the maturity amount, and minus any reduction (directly or through the use of an allowance account) for impairment or uncollectibility.

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation.

Currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates.

Derecognition is the removal of a previously recognised financial asset or financial liability from an entity's statement of financial position.

The effective interest method is a method of calculating the amortised cost of a financial asset or a financial liability (or group of financial assets or financial liabilities) and of allocating the interest income or interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments or receipts through the expected life of the financial instrument or, when appropriate, a shorter period to the net carrying amount of the financial asset or financial liability. When calculating the effective interest rate, an entity estimates cash flows considering all contractual terms of the financial instrument but does not consider future credit losses. The calculation includes all fees and points paid or received between parties to the contract that are an integral part of the effective interest rate, transaction costs, and all other premiums or discounts. In cases when it is not possible to reliably estimate the cash flows or the expected life of a financial instrument (or group of financial instruments), the entity uses the contractual cash flows over the full contractual term of the financial instrument (or group of financial instruments).

Fair value is the amount for which an asset could be exchanged, or a liability settled, between knowledgeable willing parties in an arm's length transaction.

A financial asset is:

- cash;
- a residual interest of another entity; or
- a contractual right to:
  - receive cash or another financial asset from another entity; or
  - exchange financial assets or financial liabilities with another entity under conditions that are potentially favourable to the entity.

A financial liability is any liability that is a contractual obligation to:

- deliver cash or another financial asset to another entity; or
- exchange financial assets or financial liabilities under conditions that are potentially unfavourable to the entity.

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

Accounting policies

1.7 Financial instruments (continued)

Liquidity risk is the risk encountered by an entity in the event of difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset.

Loans payable are financial liabilities, other than short-term payables on normal credit terms.

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk.

Other price risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices (other than those arising from interest rate risk or currency risk), whether those changes are caused by factors specific to the individual financial instrument or its issuer, or factors affecting all similar financial instruments traded in the market.

A financial asset is past due when a counterparty has failed to make a payment when contractually due.

Transaction costs are incremental costs that are directly attributable to the acquisition, issue or disposal of a financial asset or financial liability. An incremental cost is one that would not have been incurred if the entity had not acquired, issued or disposed of the financial instrument.

Financial instruments at amortised cost are non-derivative financial assets or non-derivative financial liabilities that have fixed or determinable payments, excluding those instruments that:

- the entity designates at fair value at initial recognition; or
- are held for trading.

Financial instruments at cost are investments in residual interests that do not have a quoted market price in an active market, and whose fair value cannot be reliably measured.

Classification

The entity has the following types of financial assets (classes and category) as reflected on the face of the statement of financial position or in the notes thereto:

Class	Category
Trade and other receivables	Financial asset measured at amortised cost
Cash and Cash Equivalents	Financial asset measured at amortised cost

The entity has the following types of financial liabilities (classes and category) as reflected on the face of the statement of financial position or in the notes thereto:

Class	Category
Trade and other payables	Financial liability measured at amortised cost
Other financial liabilities	Financial liability measured at amortised cost

Initial recognition

The entity recognises a financial asset or a financial liability in its statement of financial position when the entity becomes a party to the contractual provisions of the instrument.

The entity recognises financial assets using trade date accounting. This the date at which an agreement has been entered, instead of on the date the transaction has been finalised.

Initial measurement of financial assets and financial liabilities

The entity measures a financial asset and financial liability initially at its fair value plus transaction costs that are directly attributable to the acquisition or issue of the financial asset or financial liability.

Accounting policies

1.7 Financial instrument (continued)

Subsequent measurement of financial assets and financial liabilities

The entity measures all financial assets and financial liabilities after initial recognition using the following categories:

- Financial instruments at amortised cost.
- Financial instruments at cost.

All financial assets measured at amortised cost, or cost, are subject to an impairment review.

Gains and losses

For financial assets and financial liabilities measured at amortised cost or cost, a gain or loss is recognised in surplus or deficit when the financial asset or financial liability is derecognised or impaired, or through the amortisation process.

Impairment and uncollectibility of financial assets

The entity assesses at the end of each reporting period whether there is any objective evidence that a financial asset or group of financial assets is impaired.

Financial assets measured at amortised cost:

If there is objective evidence that an impairment loss on financial assets measured at amortised cost has been incurred, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not been incurred) discounted at the financial asset's original effective interest rate. The carrying amount of the asset is reduced through the use of an allowance account. The amount of the loss is recognised in surplus or deficit.

If, in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognised, the previously recognised impairment loss is reversed by adjusting an allowance account. The reversal does not result in a carrying amount of the financial asset that exceeds what the amortised cost would have been had the impairment not been recognised at the date the impairment is reversed. The amount of the reversal is recognised in surplus or deficit.

Financial assets measured at cost:

If there is objective evidence that an impairment loss has been incurred on an investment in a residual interest that is not measured at fair value because its fair value cannot be measured reliably, the amount of the impairment loss is measured as the difference between the carrying amount of the financial asset and the present value of estimated future cash flows discounted at the current market rate of return for a similar financial asset. Such impairment losses are not reversed.

Derecognition

Financial assets

The entity derecognises financial assets using trade date accounting. The entity derecognises a financial asset only when:

- the contractual rights to the cash flows from the financial asset expire, are settled or waived;
- the entity transfers to another party substantially all of the risks and rewards of ownership of the financial asset; or
- the entity, despite having retained some significant risks and rewards of ownership of the financial asset, has transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party, and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer. In this case, the entity :
  - derecognise the asset; and
  - recognise separately any rights and obligations created or retained in the transfer.

Accounting policies

1.7 Financial instrument (continued)

The carrying amounts of the transferred asset are allocated between the rights or obligations retained and those transferred on the basis of their relative fair values at the transfer date. Newly created rights and obligations are measured at their fair values at that date. Any difference between the consideration received and the amounts recognised and derecognised is recognised in surplus or deficit in the period of the transfer.

If the entity transfers a financial asset in a transfer that qualifies for derecognition in its entirety and retains the right to service the financial asset for a fee, it recognise either a servicing asset or a servicing liability for that servicing contract. If the fee to be received is not expected to compensate the entity adequately for performing the servicing, a servicing liability for the servicing obligation is recognised at its fair value. If the fee to be received is expected to be more than adequate compensation for the servicing, a servicing asset is recognised for the servicing right at an amount determined on the basis of an allocation of the carrying amount of the larger financial asset.

If, as a result of a transfer, a financial asset is derecognised in its entirety but the transfer results in the entity obtaining a new financial asset or assuming a new financial liability, or a servicing liability, the entity recognise the new financial asset, financial liability or servicing liability at fair value.

On derecognition of a financial asset in its entirety, the difference between the carrying amount and the sum of the consideration received is recognised in surplus or deficit.

Financial liabilities

The entity removes a financial liability (or a part of a financial liability) from its statement of financial position when it is extinguished - i.e. when the obligation specified in the contract is discharged, cancelled, expires or waived.

An exchange between an existing borrower and lender of debt instruments with substantially different terms is accounted for as having extinguished the original financial liability and a new financial liability is recognised. Similarly, a substantial modification of the terms of an existing financial liability or a part of it is accounted for as having extinguished the original financial liability and having recognised a new financial liability.

The difference between the carrying amount of a financial liability (or part of a financial liability) extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognised in surplus or deficit. Any liabilities that are waived, forgiven or assumed by another entity by way of a non-exchange transaction are accounted for in accordance with the Standard of GRAP on Revenue from Non-exchange Transactions (Taxes and Transfers).

Presentation

Interest relating to a financial instrument or a component that is a financial liability is recognised as revenue or expense in surplus or deficit.

Losses and gains relating to a financial instrument or a component that is a financial liability is recognised as revenue or expense in surplus or deficit.

A financial asset and a financial liability are only offset and the net amount presented in the statement of financial position when the entity currently has a legally enforceable right to set off the recognised amounts and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

In accounting for a transfer of a financial asset that does not qualify for derecognition, the entity does not offset the transferred asset and the associated liability.

Loans from economic entities

These include loans to and from controlling entities and controlled entity, are recognised initially at fair value plus direct transaction costs.

Loans from economic entities are classified as financial liabilities measured at amortised cost.

Accounting policies

1.7 Financial instrument (continued)

Receivables from exchange and non-exchange transactions

Trade receivables are measured at initially measured at fair value plus or minus transaction costs, and are subsequently measured at amortised cost using the effective interest rate method. Appropriate allowances for debt for estimated irrecoverable amounts are recognised in surplus or deficit when there is objective evidence that the asset is impaired. Significant financial difficulties of the debtor, probability that the debtor will enter bankruptcy or financial reorganisation, and default or delinquency in payments (more than 30 days overdue) are considered indicators that the trade receivable is impaired. The allowance recognised is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the effective interest rate computed at initial recognition.

The carrying amount of the asset is reduced through the use of an allowance account, and the amount of the deficit is recognised in surplus or deficit within operating expenses. When a trade receivable is uncollectible, it is written off against the allowance account for trade receivables. Subsequent recoveries of amounts previously written off are credited against operating expenses in surplus or deficit.

Payables from exchange transactions

Trade payables are initially measured at fair value added to or subtracted from transaction costs, and are subsequently measured at amortised cost, using the effective interest rate method.

Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and demand deposits, and other short-term highly liquid investments that are readily convertible to a known amount of cash and are subject to an insignificant risk of changes in value. These are initially measured at fair value and subsequently recognised at amortised cost.

Other financial liabilities and finance lease obligations

Financial liabilities are measured at initial recognition at fair value, and are subsequently measured at amortised cost using the effective interest rate method.

Statutory receivables are receivables that arise from legislation, supporting regulations, or similar means, and require settlement by another entity in cash or another financial asset.

Carrying amount is the amount at which an asset is recognised in the statement of financial position.

The cost method is the method used to account for statutory receivables that requires such receivables to be measured at their transaction amount, plus any accrued interest or other charges (where applicable) and, less any accumulated impairment losses and any amounts derecognised.

Nominal interest rate is the interest rate and/or basis specified in legislation, supporting regulations or similar means.

The transaction amount (for purposes of this Standard) for a statutory receivable means the amount specified in, or calculated, levied or charged in accordance with, legislation, supporting regulations, or similar means.

1.8 Tax

Current tax assets and liabilities

Current tax for current and prior periods is, to the extent unpaid, recognised as a liability. If the amount already paid in respect of current and prior periods exceeds the amount due for those periods, the excess is recognised as an asset.

Current tax liabilities (assets) for the current and prior periods are measured at the amount expected to be paid to (recovered from) the tax authorities, using the tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

Accounting policies

1.8 Tax (continued)

Deferred tax assets and liabilities

A deferred tax liability is recognised for all taxable temporary differences, except to the extent that the deferred tax liability arises from the initial recognition of an asset or liability in a transaction which at the time of the transaction, affects neither accounting surplus nor taxable profit (tax loss).

A deferred tax asset is recognised for all deductible temporary differences to the extent that it is probable that taxable surplus will be available against which the deductible temporary difference can be utilised. A deferred tax asset is not recognised when it arises from the initial recognition of an asset or liability in a transaction at the time of the transaction, affects neither accounting urplu nor taxable profit (tax loss).

A deferred tax asset is recognised for the carry forward of unused tax losses to the extent that it is probable that future taxable surplus will be available against which the unused tax losses.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

Tax expenses

Current and deferred taxes are recognised as income or an expense and included in surplus or deficit for the period, except to the extent that the tax arises from:

- a transaction or event which is recognised, in the same or a different period, to net assets; or
- a business combination.

Current tax and deferred taxes are charged or credited to net assets if the tax relates to items that are credited or charged, in the same or a different period, to net assets.

1.9 Leases

A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership. A lease is classified as an operating lease if it does not transfer substantially all the risks and rewards incidental to ownership.

When a lease includes both land and buildings elements, the entity assesses the classification of each element separately.

Finance leases - lessee

Finance leases are recognised as assets and liabilities in the statement of financial position at amounts equal to the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding liability to the lessor is included in the statement of financial position as a finance lease obligation.

The discount rate used in calculating the present value of the minimum lease payments is the interest rate implicit in the leas .

Minimum lease payments are apportioned between the finance charge and reduction of the outstanding liability. The finance charge is allocated to each period during the lease term so as to produce a constant periodic rate on the remaining balance of the liability.

Any contingent rents are expensed in the period in which they are incurred.

Operating leases - lessee

Operating lease payments are recognised as an expense on a straight-line basis over the lease term. The difference between the amounts recognised as an expense and the contractual payments are recognised as an operating lease asset or liability.

Accounting policies

1.10 Inventories (continued)

Inventories comprise of raw materials, work in progress, finished goods and consumable stores. These are initially measured at cost except where inventories are acquired through a non-exchange transaction, then their costs are their fair value as at the date of acquisition.

Subsequently inventories are measured at the lower of cost and current replacement cost.

Current replacement cost is the cost the economic entity incurs to acquire the asset on the reporting date.

The cost of inventories comprises of all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

The cost of inventories is assigned using the weighted average cost formula. The same cost formula is used for all inventories having a similar nature and use to the conomic entity.

When inventories are sold, the carrying amounts of those inventories are recognised as an expense in the period in which the related revenue is recognised. If there is no related revenue, the expenses are recognised when the goods are distributed, or related services are rendered. The amount of any write-down of inventories to net realisable value or current replacement cost and all losses of inventories are recognised as an expense in the period the write-down or loss occurs. The amount of any reversal of any write-down of inventories, arising from an increase in net realisable value or current replacement cost, are recognised as a reduction in the amount of inventories recognised as an expense in the period in which the reversal occurs.

1.11 Employee benefits

Employee benefits are all forms of consideration given by an ntity in exchange for service rendered by employees.

A qualifying insurance policy is an insurance policy issued by an insurer that is not a related party (as defined in the Standard of GRAP on Related Party Disclosures) of the reporting entity, if the proceeds of the policy can be used only to pay or fund employee benefits under a defined benefit plan and are not available to the reporting ntity's own creditors (even in liquidation) and cannot be paid to the reporting entity, unless either:

- the proceeds represent surplus assets that are not needed for the policy to meet all the related employee benefit obligations; or
- the proceeds are returned to the reporting entity to reimburse it for employee benefits already paid.

Termination benefits are employee benefits payable as a result of either:

- an entity's decision to terminate an employee's employment before the normal retirement date; or
- an employee's decision to accept voluntary redundancy in exchange for those benefits.

Other long-term employee benefits are employee benefits (other than post-employment benefits and termination benefits) that are not due to be settled within twelve months after the end of the period in which the employees render the related service.

Vested employee benefits are employee benefits that are not conditional on future employment.

A constructive obligation is an obligation that derives from an entity's actions where by an established pattern of past practice, published policies or a sufficiently specific current statement, the entity has indicated to other parties that it will accept certain responsibilities and as a result, the entity has created a valid expectation on the part of those other parties that it will discharge those responsibilities.

Accounting policies

1.11 Employee benefits (continued)

Short-term employee benefits

Short-term employee benefits are employee benefits (other than termination benefits) that are due to be settled within twelve months after the end of the period in which the employees render the related service.

Short-term employee benefits include items such as:

- wages, salaries and social security contributions;
- short-term compensated absences (such as paid annual leave and paid sick leave) where the compensation for the absences is due to be settled within twelve months after the end of the reporting period in which the employees render the related employee service;
- bonus, incentive and performance related payments payable within twelve months after the end of the reporting period in which the employees render the related service; and
- non-monetary benefits (for example, medical care, and free or subsidised goods or services such as housing, cars and cellphones) for current employees.

When an employee has rendered service to the entity during a reporting period, the entity recognise the undiscounted amount of short-term employee benefits expected to be paid in exchange for that service:

- as a liability (accrued expense), after deducting any amount already paid. If the amount already paid exceeds the undiscounted amount of the benefits, the entity recognise that excess as an asset (prepaid expense) to the extent that the prepayment will lead to, for example, a reduction in future payments or a cash refund; and
- as an expense, unless another Standard requires or permits the inclusion of the benefits in the cost of an asset.

The expected cost of compensated absences is recognised as an expense as the employees render services that increase their entitlement or, in the case of non-accumulating absences, when the absence occurs. The entity measures the expected cost of accumulating compensated absences as the additional amount that the entity expects to pay as a result of the unused entitlement that has accumulated at the reporting date.

The entity recognise the expected cost of bonus, incentive and performance related payments when the entity has a present legal or constructive obligation to make such payments as a result of past events and a reliable estimate of the obligation can be made. A present obligation exists when the entity has no realistic alternative but to make the payments.

Post-employment benefits

Post-employment benefits are employee benefits (other than termination benefits) which are payable after the completion of employment.

Post-employment benefit plans are formal or informal arrangements under which an entity provides post-employment benefits for one or more employees.

Multi-employer plans are defined contribution plans (other than state plans) or defined benefit plans (other than state plans) that pool the assets contributed by various entities that are not under common control and use those assets to provide benefits to employees of more than one entity, on the basis that contribution and benefit levels are determined without regard to the identity of the entity that employs the employees concerned.

Multi-employer plans and/or State plans

Where a plan is a defined contribution plan, the entity accounts for in the same way as for any other defined contribution plan.

Accounting policies

1.11 Employee benefits (continued)

Post-employment benefits: Defined contribution plans

Defined contribution plans are post-employment benefit plans under which an entity pays fixed contributions into a separate entity (a fund) and will have no legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay all employee benefits relating to employee service in the current and prior periods.

When an employee has rendered service to the entity during a reporting period, the ntity recognise the contribution payable to a defined contribution plan in exchange for that service:

- as a liability (accrued expense), after deducting any contribution already paid. If the contribution already paid exceeds the contribution due for service before the reporting date, the entity recognise that excess as an asset (prepaid expense) to the extent that the prepayment will lead to, for example, a reduction in future payments or a cash refund; and
- as an expense, unless another Standard requires or permits the inclusion of the contribution in the cost of an asset.

Where contributions to a defined contribution plan do not fall due wholly within twelve months after the end of the reporting period in which the employees render the related service, they are discounted. The rate used to discount reflects the time value of money. The currency and term of the financial instrument selected to reflect the time value of money is consistent with the currency and estimated term of the obligation.

Post-employment benefits: Defined benefit plans

Defined benefit plans are post-employment benefit plans other than defined contribution plans.

Actuarial gains and losses comprise experience adjustments (the effects of differences between the previous actuarial assumptions and what has actually occurred) and the effects of changes in actuarial assumptions. In measuring its defined benefit liability the ntity recognise actuarial gains and losses in surplus or deficit in the reporting period in which they occur.

Current service cost is the increase in the present value of the defined benefit obligation resulting from employee service in the current period.

Interest cost is the increase during a period in the present value of a defined benefit obligation which arises because the benefits are one period closer to settlement.

Past service cost is the change in the present value of the defined benefit obligation for employee service in prior periods, resulting in the current period from the introduction of, or changes to, post-employment benefits or other long-term employee benefits. Past service cost may be either positive (when benefits are introduced or changed so that the present value of the defined benefit obligation increases) or negative (when existing benefits are changed so that the present value of the defined benefit obligation decreases). In measuring its defined benefit liability the entity recognise past service cost as an expense in the reporting period in which the plan is amended.

The present value of a defined benefit obligation is the present value of expected future payments required to settle the obligation resulting from employee service in the current and prior periods.

The economic entity account not only for its legal obligation under the formal terms of a defined benefit plan, but also for any constructive obligation that arises from the entity's informal practices. Informal practices give rise to a constructive obligation where the entity has no realistic alternative but to pay employee benefits. An example of a constructive obligation is where a change in the entity's informal practices would cause unacceptable damage to its relationship with employees.

The amount recognised as a defined benefit liability is the net total of the following amounts:

- the present value of the defined benefit obligation at the reporting date;
- plus any liability that may arise as a result of a minimum funding requirement

Accounting policies

1.11 Employee benefits (continued)

The entity determines the present value of defined benefit obligations with sufficient regularity such that the amounts recognised in the audited annual financial statements do not differ materially from the amounts that would be determined at the reporting date.

The entity recognises the net total of the following amounts in surplus or deficit, except to the extent that another Standard requires or permits their inclusion in the cost of an asset:

- current service cost;
- interest cost;
- actuarial gains and losses;
- past service cost;
- the effect of any curtailments or settlements; and
- the effect of applying the limit on a defined benefit asset (negative defined benefit liability).

The entity uses the Projected Unit Credit Method to determine the present value of its defined benefit obligations and the related current service cost and, where applicable, past service cost. The Projected Unit Credit Method (sometimes known as the accrued benefit method pro-rated on service or as the benefit/years of service method) sees each period of service as giving rise to an additional unit of benefit entitlement and measures each unit separately to build up the final obligation.

In determining the present value of its defined benefit obligations and the related current service cost and, where applicable, past service cost, entity attributes benefit to periods of service under the plan's benefit formula. However, if an employee's service in later years will lead to a materially higher level of benefit than in earlier years, an entity attributes benefit on a straight-line basis from:

- the date when service by the employee first leads to benefits under the plan (whether or not the benefits are conditional on further service); until
- the date when further service by the employee will lead to no material amount of further benefits under the plan, other than from further salary increases.

Actuarial valuations are conducted on an annual basis by independent actuaries separately for each plan. The results of the valuation are updated for any material transactions and other material changes in circumstances (including changes in market prices and interest rates) up to the reporting date.

The entity recognises gains or losses on the curtailment or settlement of a defined benefit plan when the curtailment or settlement occurs. The gain or loss on a curtailment or settlement comprises of any resulting change in the present value of the defined benefit obligation.

Before determining the effect of a curtailment or settlement, the entity re-measure the obligation (and the related plan assets, if any) using current actuarial assumptions (including current market interest rates and other current market prices).

The entity offsets an asset relating to one plan against a liability relating to another plan when the entity has a legally enforceable right to use a surplus in one plan to settle obligations under the other plan and intends either to settle the obligations on a net basis, or to realise the surplus in one plan and settle its obligation under the other plan simultaneously.

Accounting policies

1.11 Employee benefits (continued)

Actuarial assumptions

Actuarial assumptions are unbiased and mutually compatible.

Financial assumptions are based on market expectations, at the reporting date, for the period over which the obligations are to be settled.

The rate used to discount post-employment benefit obligations reflect the time value of money. The currency and term of the financial instrument selected to reflect the time value of money is consistent with the currency and estimated term of the post- employment benefit obligations.

Post-employment benefit obligations are measured on a basis that reflects:

- estimated future salary increases;
- the benefits set out in the terms of the plan (or resulting from any constructive obligation that goes beyond those terms) at the reporting date; and
- estimated future changes in the level of any state benefits that affect the benefits payable under a defined benefit plan, if, and only if, either:
- those changes were enacted before the reporting date; or
- past history, or other reliable evidence, indicates that those state benefits will change in some predictable manner, for example, in line with future changes in general price levels or general salary levels.

Assumptions about medical costs take account of estimated future changes in the cost of medical services, resulting from both inflation and specific changes in medical costs.

1.12 Provisions and contingencies

Provisions are recognised when:

- the economic entity has a present obligation as a result of a past event;
- it is probable that an outflow of resources embodying economic benefits or service potential will be required to settle the obligation; and
- a reliable estimate can be made of the obligation.

The amount of a provision is the best estimate of the expenditure expected to be required to settle the present obligation at the reporting date.

Where the effect of time value of money is material, the amount of a provision is the present value of the expenditures expected to be required to settle the obligation.

The discount rate is a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability.

Provisions are reviewed at each reporting date and adjusted to reflect the current best estimate. Provisions are reversed if it is no longer probable that an outflow of resources embodying economic benefits or service potential will be required, to settle the obligation.

Where discounting is used, the carrying amount of a provision increases in each period to reflect the passage of time. This increase is recognised as an interest expense.

A provision is used only for expenditures for which the provision was originally recognised. Provisions are not recognised for future operating write offs.

For onerous contracts, the economic entity recognises and measures the present obligation (net of recoveries) under the contract as a provision.

Contingent assets and contingent liabilities are not recognised. Contingencies are disclosed in note 33.

Accounting policies

1.13 Commitments

Items are classified as commitments when the economic entity has committed itself to future transactions that will normally result in the outflow of cash.

Disclosures are provided for unrecognised contractual commitments.

Commitments for which disclosure is necessary to achieve a fair presentation are disclosed in a note to the financial statements, if both the following criteria are met:

- Contracts are non-cancellable or only cancellable at significant cost; and
- Contracts relate to something other than the routine, steady, state business of the entity - therefore salary commitments relating to employment contracts or social security benefit commitments are excluded.

1.14 Revenue from exchange transactions

Revenue is the gross inflow of economic benefits or service potential during the reporting period when those inflows result in an increase in net assets, other than increases relating to contributions from owners.

An exchange transaction is one in which the economic entity receives assets or services, or has liabilities extinguished, and directly gives approximately equal value (primarily in the form of goods, services or use of assets) to the other party in exchange.

Fair value is the amount for which an asset could be exchanged, or a liability settled, between knowledgeable, willing parties in an arm's length transaction.

Measurement

Revenue is measured at the fair value of the consideration received or receivable, net of trade discounts and volume rebates.

Sale of goods

Revenue from the sale of goods is recognised when all the following conditions have been satisfied:

- the economic entity has transferred to the purchaser the significant risks and rewards of ownership of the goods;
- the economic entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
- the amount of revenue can be measured reliably;
- it is probable that the economic benefits or service potential associated with the transaction will flow to the economic entity; and
- the costs incurred or to be incurred in respect of the transaction can be measured reliably.

Accounting policies

1.14 Revenue from exchange transaction (continued)

Rendering of services

When the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction is recognised by reference to the stage of completion of the transaction at the reporting date. The outcome of a transaction can be estimated reliably when all the following conditions are satisfied:

- the amount of revenue can be measured reliably;
- it is probable that the economic benefits or service potential associated with the transaction will flow to the economic entity;
- the stage of completion of the transaction at the reporting date can be measured reliably; and
- the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

When services are performed by an indeterminate number of acts over a specified time frame, revenue is recognised on a straight line basis over the specified time frame unless there is evidence that some other method better represents the stage of completion. When a specific act is much more significant than any other acts, the recognition of revenue is postponed until the significant act is executed.

When the outcome of the transaction involving the rendering of services cannot be estimated reliably, revenue is recognised only to the extent of the expenses recognised that are recoverable.

Service revenue is recognised by reference to the stage of completion of the transaction at the reporting date. Stage of completion is determined by ervices performed to date as a percentage of total services to be performed.

Interest and royalties

Revenue arising from the use by others of entity assets yielding interest is recognised when:

- It is probable that the economic benefits or service potential associated with the transaction will flow to the entity, and
- The amount of the revenue can be measured reliably.

Interest is recognised, in surplus or deficit, using the effective interest rate method.

Royalties are recognised as they are earned in accordance with the substance of the relevant agreements.

1.15 Revenue from non-exchange transactions

Revenue comprises gross inflows of economic benefits or service potential received and receivable by an entity, which represents an increase in net assets, other than increases relating to contributions from owners.

Conditions on transferred assets are stipulations that specify that the future economic benefits or service potential embodied in the asset is required to be consumed by the recipient as specified or future economic benefits or service potential must be returned to the transferor.

Control of an asset arise when the entity can use or otherwise benefit from the asset in pursuit of its objectives and can exclude or otherwise regulate the access of others to that benefit.

Exchange transactions are transactions in which one entity receives assets or services, or has liabilities extinguished, and directly gives approximately equal value (primarily in the form of cash, goods, services, or use of assets) to another entity in exchange.

Non-exchange transactions are transactions that are not exchange transactions. In a non-exchange transaction, an entity either receives value from another entity without directly giving approximately equal value in exchange, or gives value to another entity without directly receiving approximately equal value in exchange.

Restrictions on transferred assets are stipulations that limit or direct the purposes for which a transferred asset may be used, but do not specify that future economic benefits or service potential is required to be returned to the transferor if not deployed as specified.

Accounting policies

1.15 Revenue from non-exchange transactions (continued)

Stipulations on transferred assets are terms in laws or regulation, or a binding arrangement, imposed upon the use of a transferred asset by entities external to the reporting ntity.

Transfers are inflows of future economic benefits or service potential from non-exchange transactions, other than taxes.

Recognition

An inflow of resources from a non-exchange transaction recognised as an asset is recognised as revenue, except to the extent that a liability is also recognised in respect of the same inflow.

As the entity satisfies a present obligation recognised as a liability in respect of an inflow of resources from a non-exchange transaction recognised as an asset, it reduces the carrying amount of the liability recognised and recognises an amount of revenue equal to that reduction.

Measurement

Revenue from a non-exchange transaction is measured at the amount of the increase in net assets recognised by the entity.

Transfers

Apart from Services in kind, which are not recognised, the entity recognises an asset in respect of transfers when the transferred resources meet the definition of an asset and satisfy the criteria for recognition as an asset.

The ntity recognises an asset in respect of transfers when the transferred resources meet the definition of an asset and satisfy the criteria for recognition as an asset.

Transferred assets are measured at their fair value as at the date of acquisition.

1.16 Cost of sales

When inventories are sold, the carrying amount of those inventories is recognised as an expense in the period in which the related revenue is recognised. The amount of any write-down of inventories to net replacement costs and all rite offs of inventories are recognised as an expense in the period the write-down or loss occurs. The amount of any reversal of any write- down of inventories, arising from an increase in net realisable value, is recognised as a reduction in the amount of inventories recognised as an expense in the period in which the reversal occurs.

The related cost of providing services recognised as revenue in the current period is included in cost of sales.

1.17 Investment income

Investment income is recognised on a time-proportion basis using the effective interest method.

1.18 Borrowing cost

Borrowing costs are interest and other expenses incurred by an entity in connection with the borrowing of funds.

Borrowing costs are recognised as an expense in the period in which they are incurred.

1.19 Translation of foreign currencies Foreign currency transactions

A foreign currency transaction is recorded, on initial recognition in Rands, by applying to the foreign currency amount the spot exchange rate between the functional currency and the foreign currency at the date of the transaction.

At each reporting date:

- foreign currency monetary items are translated using the closing rate;
- non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction; and

Accounting policies

1.19 Translation of foreign currencies Foreign currency transactions (continued)

- non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

Exchange differences arising on the settlement of monetary items or on translating monetary items at rates different from those at which they were translated on initial recognition during the period or in previous audited annual financial statement are recognised in surplus or deficit in the period in which they arise.

Cash flows arising from transactions in a foreign currency are recorded in Rands by applying to the foreign currency amount the exchange rate between the Rand and the foreign currency at the date of the cash flow.

1.20 Comparative figures

Where necessary, comparative figures have been reclassified to conform to changes in presentation in the current yea .

1.21 Fruitless and wasteful expenditure

Fruitless expenditure means expenditure which was made in vain and would have been avoided had reasonable care been exercised.

All expenditure relating to fruitless and wasteful expenditure is recognised as an expense in the statement of financial performance in the yea that the expenditure was incurred. The expenditure is classified in accordance with the nature of the expense, and where recovered, it is subsequently accounted for as revenue in the statement of financial performance.

1.22 Irregular expenditure

Irregular expenditure as defined in section 1 of the PFMA is expenditure other than unauthorised expenditure, incurred in contravention of or that is not in accordance with a requirement of any applicable legislation, including -

(a) this Act; or
(b) the State Tender Board Act, 1968 (Act No. 86 of 1968), or any regulations made in terms of the Act; or
(c) any provincial legislation providing for procurement procedures in that provincial government.

National Treasury practice note no. 4 of 2008/2009 which was issued in terms of sections 76(1) to 76(4) of the PFMA requires the following (effective from 1 April 2008):

Irregular expenditure that was incurred and identified during the current financial and which was condoned before year end and/or before finalisation of the financial statements must also be recorded appropriately in the irregular expenditure register. In such an instance, no further action is also required with the exception of updating the note to the financial statements.

Irregular expenditure that was incurred and identified during the current financial year and for which condonement is being awaited at year end must be recorded in the irregular expenditure register. No further action is required with the exception of updating the note to the financial statements.

Where irregular expenditure was incurred in the previous financial year and is only condoned in the following financial year, the register and the disclosure note to the financial statements must be updated with the amount condoned.

Accounting policies

1.22 Irregular expenditure (continued)

Irregular expenditure that was incurred and identified during the current financial year and which was not condoned by the National Treasury or the relevant authority must be recorded appropriately in the irregular expenditure register. If liability for the irregular expenditure can be attributed to a person, a debt account must be created if such a person is liable in law. Immediate steps must thereafter be taken to recover the amount from the person concerned. If recovery is not possible, the accounting officer or Accounting Authority may write off the amount as debt impairment and disclose such in the relevant note to the financial statements. The irregular expenditure register must also be updated accordingly. If the irregular expenditure has not been condoned and no person is liable in law, the expenditure related thereto must remain against the relevant programme/expenditure item, be disclosed as such in the note to the financial statements and updated accordingly in the irregular expenditure register.

1.23 Segment information

A segment is an activity of an entity:

- that generates economic benefits or service potential (including economic benefits or service potential relating to transactions between activities of the same entity);
- whose results are regularly reviewed by management to make decisions about resources to be allocated to that activity and in assessing its performance; and
- for which separate financial information is available.

Reportable segments are the actual segments which are reported on in the segment report. They are the segments identified above or alternatively an aggregation of two or more of those segments where the aggregation criteria are met. The entity has defined its segments geographically as well per activities of the entity.

Measurement

The amount of each segment item reported is the measure reported to management for the purposes of making decisions about allocating resources to the segment and assessing its performance. Adjustments and eliminations made in preparing the entity's financial statements and allocations of revenues and expenses are included in determining reported segment surplus or deficit only if they are included in the measure of the segment's surplus or deficit that is used by management. Similarly, only those assets and liabilities that are included in the measures of the segment's assets and segment's liabilities that are used by management are reported for that segment. If amounts are allocated to reported segment surplus or deficit, assets or liabilities, those amounts are allocated on a reasonable basis.

If management uses only one measure of a segment's surplus or deficit, the segment's assets or the segment's liabilities in assessing segment performance and deciding how to allocate resources, segment surplus or deficit, assets and liabilities are reported in terms of that measure. If management uses more than one measure of a segment's surplus or deficit, the segment's assets or the segment's liabilities, the reported measures are those that management believes are determined in accordance with the measurement principles most consistent with those used in measuring the corresponding amounts in the entity's financial statements.

Accounting policies

1.24 Budget information

Economic Entity is typically subject to budgetary limits in the form of appropriations or budget authorisations (or equivalent), which is given effect through authorising legislation, appropriation or similar.

General purpose financial reporting by economic entity provides information on whether resources were obtained and used in accordance with the legally adopted budget.

The approved budget is prepared on a accrual basis and presented by functional classification. The budget for the economic entity includes all the entities approved budgets under its control.

The audited annual financial statements and the budget are on the same basis of accounting therefore a comparison with the budgeted amounts for the reporting period have been included in the Statement of comparison of budget and actual amounts .

1.25 Subsequent events

Subsequent events are those events, both favourable and unfavourable, that occur between the reporting date and the date when the financial statements are authorised for issue. Two types of events can be identified:

- those that provide evidence of conditions that existed at the reporting date (adjusting events after the reporting date); and
- those that are indicative of conditions that arose after the reporting date (non-adjusting events after the reporting date).

The economic entity adjusts the amount recognised in the financial statements to reflect adjusting events after the reporting date once the event occurred.

The economic entity discloses the nature of the event and an estimate of its financial effect or a statement that such estimate cannot be made in respect of all material non-adjusting events, where non-disclosure could influence the economic decisions of users taken on the basis of the financial statements.

Notes to the Audited Annual Financial Statements

2. New standards and interpretation

2.1 Standards and interpretations effective and adopted in the current year

In the current year, the economic entity has adopted the following standards and interpretations that are effective for the current financial year and that are relevant to its operations:

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
• GRAP 1 (amended): Presentation of Financial Statements	1 April 2020	Unlikely that there will be a material impact.
• GRAP 34: Separate Financial Statements	1 April 2020	Unlikely that there will be a material impact.
• GRAP 35: Consolidated Financial Statement	1 April 2020	Unlike that there will be a material impact.
• GRAP 110 (as amended 2016): Living and Non-living Resources	1 April 2020	Unlike that there will be a material impact.

2.2 Standards and interpretations issued, but not yet effective

The economic entity has not applied the following standards and interpretations, which have been published and are mandatory for the economic entity's accounting periods beginning on or after 01 April 2020 or later periods:

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
• GRAP 104 (amended): Financial instruments	To be determined by the Minister of Finance	Unlikely that there will be a material impact.
• GRAP 25 (amended): Employee Benefits	To be determined by the Minister of Finance	Unlike that there will be a material impact.

Notes to the Audited Annual Financial Statements

3. Inventories

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000
Raw materials components	191	154	-	-
Work in progress	4 082	4 946	-	-
Finished goods	796	735	-	14
Consumable stores	1 115 759	160 287	1 115 882	160 288
	1 120 828	**166 122**	**1 115 882**	**160 302**

As at 31 March 2021 the NHLS inventory balance amounts to R1.1 billion which is an increase of R961,3 million as compared to the previous period. The increase is mainly attributable to the NHLS having to procure sufficient inventory items to ensure the NHLS is in a position to respond to the COVID-19 pandemic in the country.

During the financial year under review there was an adjustment of R439,3 million mainly as a result of entity valuing its Covid-19 inventory to net replacement cost.

4. Receivables from exchange transactions

Trade debtors	5 112 640	4 881 325	5 109 674	4 879 329
Prepayment	64	21 959	64	21 959
Interest receivable	2 440	4 509	2 440	4 509
Other receivables	3 721	3 924	3 693	3 868
Teaching Services*	130 274	127 281	130 274	127 281
Less: Allowance for impairment on trade debtors	(3 805 975)	(3 773 320)	(3 805 631)	(3 773 230)
	1 443 164	**1 265 678**	**1 440 514**	**1 263 716**

* Teaching services are in respect of revenue generated for teaching activities provided by the NHLS employees to the different institutions of higher learning.

Outstanding debt from KwaZulu-Natal Department of Health

Included in receivables above is an amount of R2.792bn (2020: R2.720bn) owed by the (KZN (DoH) of which R2.575bn (2020: R2.585bn) has been impaired. An external audit was conducted into the amount disputed by the KZN DoH. This amount was in relation to the audit concluded that an amount of R1.8bn is owed by KZN DoH to the entity, however, the parties involved have neither agreed nor acknowledged the outcome of audit.

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

4. Receivables from exchange transactions (continued)

Outstanding debt from Gauteng Department of Health

The balance in the receivables includes an amount owed by Gauteng Department of Health amounting to R719m (2020: R1.062bn) of which R301m (2020: R401m) has been impaired.

Outstanding debt from Eastern Cape Department of Health

Included in the receivables balance above is also an amount owed by Eastern Cape Department of Health amount to R664m (2020:R477m) of which R303m (2020:R222m) has been impaired.

Outstanding debt from Northern Cape Department of Health

The balance in the receivables above also includes an amount owed by Northern Cape Department of Health amounting to R192m (2020:R98m) of which R98m (2020:R73m) has been impaired.

Trade and other receivables past due but not impaired

Trade and other receivables which are less than three months past due are not considered to be impaired. As at 31 March 2021, R1,625 304 (2020: R969,014) were past due but not impaired.

The ageing of amounts past due but not impaired is as follows:

1 month past due	1 162 139	847 089	1 159 384	845 738
2 months past due	409 743	84 416	409 667	85 884
3 months past due	53 422	37 509	53 397	37 491
	1 625 304	**969 014**	**1 622 448**	**969 113**

The maximum exposure is the carrying amount of Receivables from exchange transactions.

Trade and other receivables impaired

As at 31 March 2021, trade and other receivables of R3.806bn (2020 R3.773bn): were impaired and provided for.

The ageing of these loans is as follows:

3 to 6 months	3 805 975	3 773 230	3 805 631	3 773 230

Reconciliation of provision for impairment of trade and other receivables

Opening balance	3 773 320	3 531 479	3 773 230	3 531 479
Provision for impairment	34 295	244 055	34 041	243 965
Amounts written off as uncollectible	(1 640)	(2 214)	(1 640)	(2 214)
	3 805 975	3 773 320	3 805 631	3 773 230

5. Receivables from non-exchange transactions

Other receivables from non-exchange revenue	414 474	450 245	414 474	450 245

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000
6. Cash and cash equivalents				
Cash and cash equivalents consist of:				
Cash on hand	207	228	206	215
Bank balances	50 802	364 032	50 728	363 529
Short-term deposits	2 901 063	3 741 500	2 892 025	3 730 889
	2 952 072	**4 105 760**	**2 942 959**	**4 094 633**
Cash and cash equivalents held by the entity that are not available for use by the economic entity	625 129	550 960	625 129	550 960

The interest earned on cash at bank and short term deposits ranged from 3.76% to 5.76% (2020: 6.4% to 7.75%) and these deposits had an average maturity of 30 days.

Notes to the Audited Annual Financial Statements

7. Property plant and equipment

Economic entity	2021			2020		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
	R'000	R'000	R'000	R'000	R'000	R'000
Buildings	680 693	(65 298)	615 395	680 473	(44 062)	636 411
Buildings - air systems	250	(240)	10	51	(51)	-
Computer equipment	212 369	(141 016)	71 353	214 795	(141 210)	73 585
Furniture and fixtures	10 858	(5 159)	5 699	8 929	(5 073)	3 856
Laboratory equipment	927 211	(505 040)	422 171	461 426	(282 569)	178 857
Land	95 552	-	95 552	95 552		95 552
Leasehold property	37 587	(28 777)	8 810	31 330	(30 402)	928
Mobile units	36 544	(25 654)	10 890	24 784	(16 661)	8 123
Motor vehicles	173 210	(90 015)	83 195	95 206	(59 507)	35 699
Office Equipment	37 292	(21 498)	15 794	29 993	(16 730)	13 263
Other property plant and equipment	-	-	-	217	-	217
Plant and machinery	5 461	(3 531)	1 930	3 475	(1 799)	1 676
Sheep and horses	50	-	50	35	-	35
Total	**2 217 077**	**(886 228)**	**1 330 849**	**1 646 266**	**(598 064)**	**1 048 202**

7. Property plant and equipment (continued)

Controlling entity	2021			2020		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
	R'000	R'000	R'000	R'000	R'000	R'000
Buildings	680 693	(65 298)	615 395	680 473	(44 062)	636 411
Buildings - air systems	250	(240)	10	51	(51)	-
Computer equipment	212 124	(140 832)	71 292	214 550	(141 019)	73 531
Furniture and fixtures	10 743	(5 106)	5 637	8 814	(5 009)	3 805
Laboratory equipment	922 819	(502 424)	420 395	457 034	(279 780)	177 254
Land	95 552	-	95 552	95 552	-	95 552
Motor vehicles	173 210	(90 015)	83 195	95 206	(59 507)	35 699
Leasehold property	37 587	(28 777)	8 810	31 330	(30 402)	928
Mobile units	36 544	(25 654)	10 890	24 784	(16 661)	8 123
Office equipment	37 239	(21 454)	15 785	29 931	(16 671)	13 260
Other property, plant and equipment	-	-	-	217	-	217
Plant and machinery	5 461	(23 531)	1 930	3 475	(1 799)	
Total	**2 212 222**	**(883 331)**	**1 328 891**	**1 641 417**	**(594 961)**	**1 046 456**

Figures in Rand

7. Property plant and equipment (continued)

Reconciliation of property, plant and equipment - Economic entity - 2021

	Opening balance	Additions	Fair value adjustment	Disposals	Reclassification	Change in Accounting Estimates	Depreciation	Total
	R'000	R'000	R'000	R'000	R'000	R'000	R'000	R'000
Buildings	636 411	481	-	-	(244)	-	(21 253)	615 395
Buildings - air systems	-	-	-	-	69	-	(59)	10
Computer equipment	73 585	21 262	-	(59)	(254)	20 383	(43 564)	71 353
Furniture and fixtures	3 856	1 374	-	(6)	211	917	-653	5 699
Laboratory equipment	178 857	273 138	-	(3 099)	(6)	102 510	(129 229)	422 171
Land	95 552	-	-	-	-	-	-	95 552
Leasehold property	928	2 625	-	-15	187	8 006	(2 921)	8 810
Mobile units	8 123	1 338	-	-		5 382	(3 953)	10 890
Motor vehicles	35 699	79 899	-	-56	-	834	(33 181)	83 195
Office equipment	13 263	5 495	-	-95	289	1 894	(5 052)	15 794
Other property plant and equipment	217	-	-	-	(217)	-	-	-
Plant and machinery	1 676	430	-	-	-	599	-775	1 930
Sheep and horses	35	-	15	-	-	-	-	50
	1 048 202	**386 042**	**15**	**(3 330)**	**35**	**140 525**	**(240 640)**	**1 330 849**

Figures in Rand

7. Property plant and equipment (continued)

Reconciliation of property, plant and equipment - Economic entity - 2020

	Opening balance	Additions	Fair value adjustment	Disposals	Reclassification	Depreciation	Total
	R'000	R'000	R'000	R'000	R'000	R'000	R'000
Buildings	654 620	3 587	-	(592)	592	(21 796)	636 411
Buildings - air systems	392	2 320	-	-	(2 240)	(472)	-
Computer equipment	84 619	33 118	-	(1 363)	32	(42 821)	73 585
Furniture and fixtures	3 500	673	-	(8)	17	(326)	3 856
Laboratory equipment	173 535	60 367	-	(1 267)	2 179	(55 957)	178 857
Land	95 552	-	-	-	-	-	95 552
Leasehold property	1 311	335	-	(497)	-	(221)	928
Mobile units	8 561	1 862	-	(144)	-	(2 156)	8 123
Motor vehicles	49 727	3 181	-	(640)	-	(16 569)	35 699
Office equipment	14 787	3 325	-	(190)	(579)	(4 080)	13 263
Other property, plant and equipment	535	55	-	-	(373)		217
Plant and machinery	1 633	504	-	-	-	(461)	1 676
Sheep and horses	58	-	(23)	-	-	-	35
	1 088 830	**109 327**	**(23)**	**(4 701)**	**(372)**	**(144 859)**	**1 048 202**

Notes to the Audited Annual Financial Statements

Figures in Rand

7. Property plant and equipment (continued)

Reconciliation of property, plant and equipment - Controlling entity - 2021

	Opening balance	Additions	Disposals	Reclassification	Change in Accounting Estimates	Depreciation	Total
	R'000	R'000	R'000	R'000	R'000	R'000	R'000
Buildings	636 411	481		(244)		(21 253)	615 395
Buildings - air systems	-	-	-	69	-	(59)	10
Computer equipment	73 531	21 262	(59)	(254)	20 345	(43 533)	71 292
Furniture and fixtures	3 805	1 374	-6	211	887	(634)	5 637
Laboratory equipment	177 254	273 138	(3 099)	(6)	101 810	(128 702)	420 395
Land	95 552	-	-	-	-	-	95 552
Leasehold property	928	2 625	-15	187	8 006	(2 921)	8 810
Mobile units	8 123	1 338	-	-	5 382	(3 953)	10 890
Motor vehicles	35 699	79 899	-56	-	834	(33 181)	83 195
Office equipment	13 260	5 495	-95	289	1 882	(5 046)	15 785
Other property plant and equipment	217	-	-	(217)	-	-	-
Plant and machinery	1 676	430	-	-	599	(775)	1 930
	1 046 456	**386 042**	**(3 330)**	**35**	**139 745**	**(240 057)**	**1 328 891**

Figures in Rand

7. Property plant and equipment (continued)

Reconciliation of property, plant and equipment - Controlling entity - 2020

	Opening balance	Additions	Disposals	Reclassification	Depreciation	Total
	R'000	R'000	R'000	R'000	R'000	R'000
Buildings	654 620	3 587	(592)	592	(21 796)	636 411
Buildings - air systems	392	2 320	-	(2 240)	(472)	-
Computer equipment	84 534	33 119	(1 363)	31	(42 790)	73 531
Furniture and fixtures	3 482	672	(8)	17	(358)	3 805
Laboratory equipment	171 992	60 108	(1 267)	2 179	(55 758)	177 254
Land	95 552	-	-	-	-	95 552
Leasehold property	1 311	335	(497)		(221)	928
Mobile units	8 561	1 862	(144)	-	(2 156)	8 123
Motor vehicles	49 727	3 181	(640)	-	(16 569)	35 699
Office equipment	14 784	3 325	(190)	(579)	(4 080)	13 260
Other property, plant and equipment	535	55	-	(373)	-	217
Plant and machinery	1 633	504	-	-	(461)	1 676
	1 087 123	**109 068**	**(4 701)**	**(373)**	**(144 661)**	**1 046 456**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

7. Property plant and equipment (continued)

Carrying value of assets pledged as security:

Assets subject to finance lease (Net carrying amount)

Motor vehicles	15 353	31 273	15 353	31 273

Expenditure incurred to repair and maintain property, plant and equipment

Expenditure incurred to repair and maintain property, plant and equipment included in Statement of Financial Performance				
Office Equipment	6 954	5 121	6 937	5 121
Buildings	41 075	49 992	41 063	49 978
Motor vehicles	411	621	411	621
Laboratory equipment	50 988	49 306	50 081	48 325
	99 428	**105 040**	**98 492**	**104 045**

Sheep and horse

As at 31 March 2021, the economic entity owns 50 sheep (2020: 51) and 59 horses (2020: 59). The sheep blood are used for the testing of anti-venom. The horses are used for the production of anti-venom. The sheep and horses meet the definition of an asset and they have been classified as property, plant and equipment in terms of GRAP 17.

8. Intangible assets

Economic entity	2021			2020		
	Cost	Accumulated amortisation and accumulated impairment	Carrying value	Cost	Accumulated amortisation and accumulated impairment	Carrying value
	R'000	R'000	R'000	R'000	R'000	R'000
Computer software	9 638	(3 153)	6 485	148 017	(143 242)	4 775
Patents	60	(39)	21	60	(36)	24
Total	**9 698**	**(3 192)**	**6 506**	**148 077**	**(143 278)**	**4 799**

Controlling entity	2021			2020		
	Cost	Accumulated amortisation and accumulated impairment	Carrying value	Cost	Accumulated amortisation and accumulated impairment	Carrying value
	R'000	R'000	R'000	R'000	R'000	R'000
Computer software	9 638	(3 153)	6 485	148 017	(143 242)	4 775
Patents	60	(39)	21	60	(36)	24
Total	**9 698**	**(3 192)**	**6 506**	**148 077**	**(143 278)**	**4 799**

Notes to the Audited Annual Financial Statements

8. Intangible assets (continued)

Reconciliation of intangible assets - Economic entity - 2021

	Opening balance	Additions	Reclassification	Change in Accounting Estimate	Amortisation	Total
	R'000	R'000	R'000	R'000	R'000	R'000
Computer software	4 775	2 616	-252	1 007	(1 661)	6 485
Patents	24	-	-	-	(3)	21
	4 799	**2 616**	**-252**	**1 007**	**(1 664)**	**6 506**

Reconciliation of intangible assets - Economic entity - 2020

	Opening balance	Additions	Disposals	Amortisation	Total
	R'000	R'000	R'000	R'000	R'000
Computer software	937	4 479	-	(641)	4 775
Patents	27	-	-	(3)	24
	964	**4 479**	**-**	**(644)**	**4 799**

Reconciliation of intangible assets - Controlling entity - 2021

	Opening balance	Additions	Reclassification	Change in Accounting Estimate	Amortisation	Total
	R'000	R'000	R'000	R'000	R'000	R'000
Computer software	4 775	2 616	(252)	1 007	(1 661)	6 485
Patents	24	-	-	-	(3)	21
	4 799	**2 616**	**-252**	**1 007**	**(1 664)**	**6 506**

Reconciliation of intangible assets - Controlling entity - 2020

	Opening balance	Additions	Disposals	Amortisation	Total
	R'000	R'000	R'000	R'000	R'000
Computer software	937	4 479	-	(641)	4 775
Patents	27	-	-	(3)	24
	964	**4 479**		**(644)**	**4 799**

Notes to the Audited Annual Financial Statements

8. Intangible assets (continued)

*Reclassification represent corrections made in current year of intangible assets incorrectly classifiied as property, plant and equipment.

9. Investment in controlled entity

Name of company	Held by	% holding 2021	% holding 2020	Carrying amount 2021	Carrying amount 2020
		R'000	R'000	R'000	R'000
South African Vaccine Producers (Pty) Limited		100.00%	100.00%	-	-

carrying amounts of controlled entities are shown net of impairment losses.

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

10. Loans to economic entity

Controlled entities

South African Vaccine Producers (Pty) Ltd	-	-	31 157	32 999
	-	-	31 157	32 999
Impairment of loans to controlled entity	-	-	(31 157)	(32 999)
	-	-	-	-

The Controlling entity has subordinated it's rights to claim payments of debts of R31,157m (2020: R32,999m) owing to it by South African Vaccine Producers (Pty) Limited until the assets of the subsidiary, fairly valued, exceed its liabilities. The report of the Accounting Authority contains further details of the subsidiary.

Loan to SAVP impaired

As of 31 March 2021, loans (including share capital) to the controlled entity of R31,157m (2020: R32 999m) were impaired and provided for.

11. Other financial liabilities

At amortised cost

Onerous contract	4 920	9 880	4 920	9 880

Non-current liabilities

At amortised cost	-	5 056	-	5 056

Current liabilities

At amortised cost	4 920	4 824	4 920	4 824

12. Finance lease obligation

Minimum lease payments due

- within one year	19 802	21 193	19 802	21 193
- in second to fifth year inclusive	103	20 090	103	20 090
	19 905	41 283	19 905	41 283
less: future finance charges	(1 076)	(4 153)	(1 076)	(4 153)
Present value of minimum lease payments	**18 829**	**37 130**	**18 829**	**37 130**

Present value of minimum lease payments due

- within one year	18 727	18 148	18 727	18 148
- in second to fifth year inclusive	102	18 982	102	18 982
	18 829	**37 130**	**18 829**	**37 130**
Non-current liabilities	102	18 982	102	18 982
Current liabilities	18 727	18 148	18 727	18 148
	18 829	**37 130**	**18 829**	**37 130**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

It is economic entity's policy to lease certain motor vehicles and equipment under finance leases.

The average lease term was five years and the fixed borrowing rate is 11%.

Interest rates are fixed at the contract date. All leases have fixed repayments and no arrangements have been entered into for contingent rent.

The depreciation on leased assets amounts to R63.9 million (2020: R47.9 million).

The economic entity's obligations under finance leases are secured by the lessor's charge over the leased assets. Refer note 7.

13. Payables from exchange transactions

Trade payables	411 763	208 802	411 318	208 402
Payments received in advanced - contract in process	87	2 004		
Debtors with credit balances	134 615	172 145	134 615	172 145
Accrued expenses	568 349	173 686	567 842	173 491
Other payables **	25 358	169 239	25 358	169 239
	1 140 172	**725 876**	**1 139 133**	**723 277**

* Trade payables are non-interest bearing and are normally settled on 30-day payment terms.

** Other payables are made up of employee cost related liabilities and other sundry payables.

14. Post retirement medical benefit plan

Post retirement medical aid plan

NHLS provides post-employment healthcare benefits. Members who joined NHLS before 1 January 2003, and KwaZulu-Natal members who joined NHLS before 1 October 2006 are eligible for a subsidy of medical scheme contributions in retirement.

The amounts recognised in the statement of financial position are as follows:

Carrying value				
Present value of the defined benefit obligation-wholly unfunded	(919 388)	(953 397)	(919 388)	(953 397)
Non-current liabilities	(881 878)	(918 492)	(881 878)	(918 492)
Current liabilities	(37 510)	(34 905)	(37 510)	(34 905)
	(919 388)	**(953 397)**	**(919 388)**	**(953 397)**

Changes in the present value of the defined benefit obligation are as follows:

Opening balance	953 397	988 415	953 397	988 415
Contributions by plan participants	(36 728)	(32 438)	(36 728)	(32 438)
Net expense (income) recognised in the statement of financial performance	2 719	(2 580)	2 719	(2 580)
	919 388	**953 397**	**919 388**	**953 397**
	'000	'000	'000	'000
Net expense recognised in the statement of financial performance				
Current service cost	19 553	22 335	19 553	22 335
Interest cost	106 531	106 889	106 531	106 889
Actuarial (gains) losses	(123 365)	(131 804)	(123 365)	(131 804)
	2 719	**(2 580)**	**2 719**	**(2 580)**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

14. Post retirement medical benefit plan (continued)

Calculation of actuarial gains and losses				
Change in real discount rate	48 777	113 382	48 777	113 382
Lower than expected healthcare cost inflation including changes in members benefit options	21 798	153	21 798	153
Unexpected changes in membership	52 790	18 269	52 790	18 269
	123 365	**131 804**	**123 365**	**131 804**

Key assumptions used

For practical reasons, the economic assumptions are determined before the valuation date. The economic assumptions used in this valuation are based on market information as at end February 2021. The economic assumptions have been set based on the duration of the liability as at 31 March 2020. At that date, the duration of the liablity was 15.8 (2020:17.2) years; and therefore a duration of 16 (2020:17) years was used to set the economic assumptions. Assumptions used at the reporting date:

Discount rates used	12 70 %	11 40 %	12 70 %	11 40 %
CPI inflation rate	7.50%	6.60%	7.50%	6.60%
Salary inflation	9 00 %	8 10 %	9 00 %	8 10 %
Expected increase in healthcare costs	9 50 %	8 60 %	9 50 %	8 60 %

Discount rate:

The discount rate of 12.7% (2020:11.4%) per annum is primarily determined by reference to current market yields on government bonds.

Consumer Price Index Inflation:

While not used in the valuation, the actuaries have assumed the underlying future rate of consumer price index inflation (CPI inflation) to be 7.5% (2020: 6.6%) per annum. This assumption has been based on the relationship between the nominal bond curve and the real bond yield.

Income at Retirement:

Income at retirement is relevant to the extent that the contribution tables are based on income. The actuaries have assumed at that an individual member's income would increase by 9.0% (2020:8.1%) per annum, based on the underlying assumption that individual remuneration increase including merit and promotional increases would exceed CPI inflation by an average of 1.5% per annum over the long term. The actuarial assumption is that income at retirement would be 65% of final salary.

Healthcare cost inflation:

The current contribution tables of the medical schemes would continue to apply in the future, with allowances of inflationary increases of 9.5% per annum. In consultation with NHLS, assumptions made by the actuaries state that healthcare cost inflation exceed CPI inflation by an average of 2.00% per annum over the long term.

Sensitivity analysis

Assumed healthcare cost trends rates have a significant effect on the amounts recognised in surplus or deficit. A one percentage point change in assumed healthcare cost trends rates would have the following effects:

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

14. Post retirement medical benefit plan (continued)

	2021 One percentage point increase	2021 One percentage point decrease	2020 One percentage point Increase	2020 One percentage point decrease
Effect on the aggregate of the service cost and interest cost	16 340	(13 701)	20 997	(17 040)
Effect on defined benefit obligation	147 654	(117 613)	147 081	(109 044)

Amounts for the current and previous four years are as follows:

	2021	2020	2019	2018	2017
Defined benefit obligation	919 388	953 397	988 415	1 000 034	1 022 679

Defined contribution plan

It is the policy of the economic entity to provide retirement benefits to all its employees. A number of defined contribution provident funds, all of which are subject to the Pensions Funds Act exist for this purpose.

The economic entity is under no obligation to cover any unfunded benefits.

15.Unspent conditional grants and receipts

Unspent conditional grants and receipts comprises of:

Unspent conditional grants and receipts				
Research grants	17 548	35 581	17 548	35 581
Movement during the year				
Balance at the beginning of the year	35 581	28 669	35 581	28 669
Additions during the year	21 656	21 832	21 656	21 832
Income recognition during the year	(39 689)	(14 920)	(39 689)	(14 920)
	17 548	**35 581**	**17 548**	**35 581**

16.Provisions

Reconciliation of provisions - Economic entity - 2021

	Opening Balance	Additions	Utilised during the year	Reversed during the year	Total
Bonus provision [1]	547	2 303	(2 272)	-	578
DoH utility charges provision [2]	418 398	259 602	-	(485 759)	192 241
Leave pay provision [3]	258 516	-	-	-274	318 199
Salaries provision [4]	163 671	74 745	(14 788)	-	163 671
Student bursary provision [5]	260	65	-260	-	65
	841 392	**336 715**	**(17 320)**	**(486 033)**	**674 754**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

16. Provisions (continued)

Reconciliation of provisions - Economic entity - 2020

	Opening Balance	Additions	Utilised during the year	Reversed during the year	Total
Bonus provision [1]	529	2 085	(2 067)		547
DoH utility charges provision [2]	375 336	43 062			418 398
Leave pay provision [3]	232 099	55 715	(17 955)	(11 343)	258 516
Salaries provision [4]	163 671				163 671
Student bursary provision [5]	780	260	-780		260
	772 415	**101 122**	**(20 802)**	**(11 343)**	**841 392**

Reconciliation of provisions - Controlling entity - 2021

	Opening Balance	Additions	Utilised during the year	Reversed during the year	Total
Bonus provision [1]	547	2 303	(2 272)		578
DoH utility charges provision [2]	418 398	259 602		(485 759)	192 241
Leave pay provision [3]	258 516	74 197	(14 788)	274	318 199
Salaries provision [4]	163 671				163 671
Student bursary provision [5]	260	65	-260		65
	841 392	**336 167**	**(17 320)**	**(485 485)**	**674 754**

Reconciliation of provisions - Controlling entity - 2020

	Opening Balance	Additions	Utilised during the year	Reversed during the year	Total
Bonus provision [1]	529	2 085	(2 067)		547
DoH utility charges provision [2]	375 336	43 062			418 398
Leave pay provision [3]	232 099	55 715	(17 955)	(11 343)	258 516
Salaries provision [4]	163 671				163 671
Student bursary provision [5]	780	260	-780		260
	772 415	**101 122**	**(20 802)**	**(11 343)**	**841 392**

[1] The bonus provision is made up of the following:

- Certain employees in bands D and above who are on the cost to company package and elect to structure part of their package as a 13th cheque. The provision is utilised when employees become entitled to and are paid for their services to the entity. The bonus payable is determined by applying a specific formula based on the employees' total cost to company; and
- A 13th cheque for employees in bands A to C which is payable in December each year.

[2] The DoH utility charges provision relates to utilities and maintenance fees owing to the DoH for various provincial hospital facilities around the country. With the exception of KwaZulu-Natal, a reclassification adjustment of R228 million from provisions to accruals for all other eight provinces. During the 2020/21 financial year, the NHLS developed and implement a new utilities policy that was approved by all the relevant structures. The policy resulted in the reversal of all the utility provisions and accruals older than three years as at the 31 March 2021. The policy also defined and provided guidelines for the amounts to be disclosed as the utilities accrual as well as the utilities provision in the Annual Financial Statements.

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

16 Provisions (continued)

[3] The leave pay provision relates to vesting leave pay to which employees may become entitled upon leaving the employment of the economic entity. The provision arises as employees render a service that increases their entitlement to future compensated leave and is calculated based on an employee's total cost of employment. The provision is utilised when employees become entitled to and are paid for the accumulated leave pay or utilise compensated leave due to them.

[4] The economic entity has an agreement with Walter Sisulu University wherein the NHLS is required to pay part of the salaries for pathological academic staff. The amount has been estimated in the absence of actual figures and invoices.

[5] Student bursary provisions relate to contractual commitments made by the economic entity by year end to fund student education for which the amount cannot yet be determined. The economic entity makes a provision based of the number of students awarded bursaries and amounts estimated using historical experiences.

17. Deferred tax

Deferred tax liability				
Property plant and equipment	(389)	(242)	-	-

The deferred tax assets and the deferred tax liability relate to income tax in the same jurisdiction, and the law allows net settlement. Therefore, they have been offset in the statement of financial position as follows:

Reconciliation of deferred tax liability				
At beginning of year	(242)	5	-	-
Taxable temporary difference movement on tangible fixed assets	(147)	(247)	-	-
	(389)	**(242)**	**-**	**-**

18. Revenue

Sale of goods	25 642	29 117	-	-
Rendering of services	9 752 964	8 428 133	9 752 964	8 428 133
Miscellaneous other revenue	42 383	7 909	42 383	7 909
Government grants and subsidies	855 584	785 506	855 584	785 506
	10 676 573	**9 250 665**	**10 650 931**	**9 221 548**

The amount included in revenue arising from exchanges of goods or services are as follows:				
Sale of goods	25 642	29 117	-	-
Rendering of services	9 752 964	8 428 133	9 752 964	8 428 133
*Miscellaneous other revenue	42 383	7 909	42 383	7 909
	9 820 989	**8 465 159**	**9 795 347**	**8 436 042**

* Miscellaneous other revenue are generated when the NHLS recovers funds for rental lease agreements, hosts conferences and other charges which need to be recovered from the use of its own facilities such as those used by Contract Laboratory Services. In the current financial the increase is due to billing for COVID-19 Antigen goods provided to the Provincial Departments of Health.

The amount included in revenue arising from non exchange transactions is as follows:				
Transfer revenue				
Government grants and subsidies	855 584	785 506	855 584	785 506
	855 584	**785 506**	**855 584**	**785 506**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000
19. Cost of sale				
Direct employee costs	3 903 058	3 644 605	3 887 822	3 629 188
Direct depreciation and impairments	109 110	142 917	109 410	142 741
Direct material expenses	6 559 713	3 577 381	6 552 027	3 567 620
	10 571 881	**7 365 003**	**10 549 259**	**7 339 549**
20. Other income				
Discount received	305	608	305	607
Fees earned	2 284	970	2 284	970
Grant income recognised	176 123	102 880	176 123	102 880
Internal recoveries	17 163	7	17 163	7
Public contributions and Donations	250 869	4 604	250 869	4 604
Utilities provision write off *	485 759	-	485 759	-
Royalties received	2 063	4 407	2 063	4 407
Sundry income	826	3 444	826	3 444
Teaching income	87 532	63 761	87 532	63 761
	1 022 924	**180 681**	**1 022 924**	**180 680**

* During the 2020/21 financial period the NHLS received the funding to the amount of R251 million from the Solidarity Fund to assist the NHLS in its response to the COVID-19 pandemic. The funds were used to purchase COVID-19 used by the NHLS to perform COVID-19 testing.

** The Utilities provision write off is in relation to the Utilities policy that was implementated for the first time in the current financial year that resulted in the written off being processed due to the prescription period.

The amount included in other revenue arising from exchanges of goods or services are as follows:				
Discount received	305	608	305	607
Fees earned	2 284	970	2 284	970
Internal recoveries	17 163	7	17 163	7
Utilities provision write off	485 759	-	485 759	-
Royalties received	2 063	4 407	2 063	4 407
Sundry income	826	3 444	826	3 444
Teaching income	87 532	63 761	87 532	63 761
	595 932	**73 197**	**595 932**	**73 196**
Transfers				
Grant income recognised	176 123	102 880	176 123	102 880
Public contributions and donations	250 869	4 604	250 869	4 604
	426 992	**107 484**	**426 992**	**107 484**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

21. Operating (deficit) surplus

Operating (deficit) surplus for the year is stated after accounting for the following:

Operating lease charges				
Premises				
• Straight-lined	4 576	4 082	4 462	4 082
Motor vehicle				
• Straight-lined	3 832	3 832	-	-
Equipment				
• Straight-lined	42 470	37 245	42 323	37 078
	47 046	**45 159**	**46 785**	**44 992**
Loss on sale of property plant and equipment	1 493	3 815	1 493	3 815
Amortisation on intangible assets	1 151	543	1 151	543
Depreciation on property, plant and equipment	100 409	144 348	99 830	144 119
Employee costs	**4 202 399**	**3 930 643**	**4 186 298**	**3 914 816**

22. Interest income

Interest revenue				
Bank	128 952	288 596	128 453	287 967
Interest received - debtors	34 753	27 245	34 733	27 245
	163 705	**315 841**	**163 186**	**315 212**

23. Interest expense

Bank	15		15	
Finance leases	3 681	6 142	3 681	6 142
Late payment of tax	1	125	1	
Other interest paid	-	11	-	11
	3 697	**6 278**	**3 697**	**6 153**

24. Taxation

Major components of the tax expense				
Current				
Local income tax - current period	333	1 109	-	-
Local income tax - recognised in current tax for prior periods	-	(539)	-	-
	333	570	-	-
Deferred				
Originating and reversing temporary differences	147	246	-	-
	480	**816**	**-**	**-**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

24. Taxation (continued)

Reconciliation of the tax expense

Reconciliation between applicable tax rate and average effective tax rate.

Applicable tax rate	28.00%	28.00%	-%	-%
Other	-%	4 36 %	-%	-%
	28 00 %	**32 36 %**	**-%**	**-%**

25. Employee related costs

Basic	3 081 398	2 898 761	3 069 650	2 887 152
Bonus	161 735	156 949	160 990	156 116
Defined contribution plans	250 790	242 117	249 667	241 011
External bursaries	375	4 689	345	4 689
Leave pay provision charge	76 896	44 352	76 734	44 300
Long-term benefits - incentive scheme	3 405	3 213	3 380	3 203
Medical aid - company contributions	232 250	217 290	231 090	216 187
Other allowances	211 875	193 825	211 875	193 825
Other short term costs	131 804	123 924	131 098	123 217
SDL	25 469	25 029	25 328	24 891
Training	146	148	17	11
UIF	14 828	12 761	14 761	12 694
WCA	11 428	7 585	11 363	7 520
	4 202 399	3 930 643	4 186 298	3 914 816

Employee costs are split into cost of sales and general expenses as follows:

Cost of sales - employee costs	3 903 058	3 644 605	3 887 822	3 629 188
General expenses - employee costs	299 341	286 038	298 476	285 628
	4 202 399	3 930 643	4 186 298	3 914 816

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000
26. Operating expense				
Advertising	889	308	895	308
Archiving and Storage	8 497	6 498	8 497	6 498
Auditors remuneration	12 511	11 393	12 511	11 059
Bad debts written off	1 640	2 056	1 640	2 056
Bank charges	9 766	12 594	9 725	12 544
Cleaning	8 107	4 793	8 094	4 783
Computer expenses	2 415	1 049	2 414	1 049
Conferences and seminars	56	608	56	588
Consulting and professional fee	67 873	39 582	67 717	39 467
Consumables	18 335	16 646	18 303	16 638
Contributions to debt impairment provision	32 654	241 871	30 559	239 543
Debt collection	952	1 013	952	1 013
Delivery expenses	2 817	1 040	2 806	1 037
Depreciation, amortisation and impairments	(8 315)	1 974	2 219	1 921
Discount allowed	35 674	20 642	35 674	20 642
Employee costs	299 341	286 038	298 476	285 628
Entertainment	2	21	2	21
Fines and penalties	(27)	2	(27)	2
Insurance	9 173	6 956	9 173	6 956
Lease rentals on operating lease	41 000	38 733	40 875	38 633
Legal expenses	20 494	17 343	20 492	17 322
Loss on disposal of assets and liabilities	3 335	3 815	3 335	3 815
Gain or loss on exchange differences	2 127	3 880	2 127	3 870
Medical expenses		563		563
Minor assets	8 929	5 871	8 929	5 879
Motor vehicle expenses	11 093	563	11 093	563
Other expenses	904	1 172	917	1 017
Packaging	9 552	9 329	9 407	9 289
Petrol and oil	10 447	7 297	10 447	7 297
Postage and courier	329	133	329	133
Printing and stationery	44 624	41 300	44 585	41 088
Project Management expense	690	101	690	101
Promotions	2	411	2	411
Promotions and sponsorships	38	37	38	37
Repairs and maintenance	48 442	55 733	48 412	55 719
Research Trust	5	26	5	26
Royalties and license fees	1 582	3 329	1 582	3 329
Security	4 559	1 202	4 559	1 202
Software development expenses	15 546	6 373	15 546	6 373
Software expenses	176 177	132 039	176 177	132 039
Staff welfare	6 078	9 827	5 911	9 700
Subscriptions and membership fees	4 763	579	4 740	540
Telephone and fax	124 541	88 054	124 459	87 949
Training	26 077	43 787	26 077	43 787
Travel - local	11 412	36 918	11 412	36 917
Travel - overseas	24	578	24	578
Utilities	157 717	136 323	157 717	136 323
	1 232 850	**1 300 432**	**1 228 925**	**1 296 253**
27. Auditors' remuneration				
Audit Fees - current year	11 533	8 755	11 533	8 405
Adjustment for previous year	-	2 096	-	2 112
Fees for other services	978	542	978	542
	12 511	**11 393**	**12 511**	**11 059**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000
28. Depreciation and amortisation				
Depreciation and amortisation - Cost of sales	109 110	142 917	109 410	142 741
Depreciation and amortisation - General expense	(8 315)	1 974	(8 429)	1 921
	100 795	**144 891**	**100 981**	**144 662**
29. Cash (used in) generated from operations				
Surplus (deficit) for the year	54 309	1 074 635	55 160	1 075 485
Adjustments for:				
Depreciation and amortisation	100 757	145 781	100 967	145 307
Loss on sale of assets and liabilities	3 335	3 815	3 335	3 815
Fair value adjustments	(15)	23	-	-
Finance costs	3 681	6 142	3 681	6 142
Debt impairment	32 654	243 927	30 559	241 599
Movements in retirement benefit assets and liabilities	(34 009)	(35 018)	(34 009)	(35 018)
Movements in provision	(166 638)	68 977	(166 638)	68 977
Movement in tax receivable and payable	333	(231)	-	-
Annual charge for deferred tax	147	246	-	-
Other non-cash items	227	258	214	370
Changes in working capital:				
Inventories	(954 706)	(862)	(955 580)	(3 931)
Receivables from exchange transactions	(247 670)	522 900	(244 887)	524 716
Other receivables from non-exchange transaction	35 771	17 375	35 771	17 375
Payables from exchange transactions	451 826	(15 976)	453 386	(17 996)
VAT	(57)	(121)		
Unspent conditional grants and receipt	(18 033)	6 912	(18 033)	6 912
	(738 088)	**2 038 783**	**(736 074)**	**2 033 753**
30. Tax paid				
Balance at beginning of the year	(1 693)	(1 924)	-	-
Current tax for the year recognised in surplus or deficit	(333)	(570)	-	-
Balance at end of 31 March 2021	2 026	1 693	-	-
	-	**(801)**	**-**	**-**

Notes to the Audited Annual Financial Statements

31. Financial instruments disclosure

Categories of financial instruments

Economic entity - 2021

Financial assets

	R'000	R'000
	At amortised cost	**Total**
Receivables from exchange transactions	1 439 711	1 439 711
Receivables from non-exchange transactions	414 474	414 474
Cash and cash equivalents	2 952 072	2 952 072
	4 806 257	**4 806 257**

Financial liabilities

	At amortised cost	**Total**
Other financial liabilities	4 920	4 920
Payables from exchange transactions	1 115 861	1 115 861
Finance lease liability	18 829	18 829
	1 139 610	**1 139 610**

Economic entity - 2020

Financial assets

	At amortised cost	**Total**
Receivables from exchange transactions	1 240 405	1 240 405
Receivables from non-exchange transactions	450 245	450 245
Cash and cash equivalents	4 105 760	4 105 760
	5 796 410	**5 796 410**

Financial liabilities

	At amortised cost	**Total**
Other financial liabilities	9 880	9 880
Payables from exchange transactions	707 050	707 050
Finance lease liability	37 130	37 130
	754 060	**754 060**

Controlling entity - 2021

Financial assets

	At amortised cost	**Total**
Receivables from exchange transactions	1 437 168	1 437 168
Receivables from non-exchange transactions	414 474	414 474
Cash and cash equivalents	2 942 959	2 942 959
	4 794 601	**4 794 601**

Notes to the Audited Annual Financial Statements

31. Financial instruments disclosure (continued)

Financial liabilities

	R'000	R'000
	At amortised cost	**Total**
Other financial liabilities	4 920	4 920
Payables from exchange transactions	1 114 820	1 114 820
Finance lease liability	18 829	18 829
	1 138 569	**1 138 569**

Controlling entity - 2020

Financial assets

	At amortised cost	**Total**
Receivables from exchange transactions	1 238 608	1 238 608
Receivables from non-exchange transactions	450 245	450 245
Cash and cash equivalents	4 094 633	4 094 633
	5 783 486	**5 783 486**

Financial liabilities

	At amortised cost	**Total**
Other financial liabilities	13 940	13 940
Payables from exchange transactions	704 051	704 051
Finance lease liability	37 130	37 130
	755 121	**755 121**

Financial instruments in Statement of financial performance

Economic entity - 2021

	At amortised cost	**Total**
Interest income	163 705	163 705
Interest expense	(3 697)	(3 697)
	160 008	**160 008**

Economic entity - 2020

	At amortised cost	**Total**
Interest income	315 841	315 841
Interest expense	(6 278)	(6 278)
	309 563	**309 563**

Notes to the Audited Annual Financial Statements

31. Financial instruments disclosure (continued)

Controlling entity - 2021

	R'000	R'000
	At amortised cost	Total
Interest income	163 186	163 186
Interest expense	(3 697)	(3 697)
	159 489	**159 489**

Controlling entity - 2020

	At amortised cost	Total
Interest income	315 212	315 212
Interest expense	(6 153)	(6 153)
	309 059	**309 059**

32. Commitments

	Economic entity		Controlling entity	
	2021 '000	2020 '000	2021 '000	2020 '000
Authorised capital expenditure				
Already contracted and approved				
• Property, plant and equipment	205 348	78 387	205 348	78 387
Not yet contracted for and approved				
• Property plant and equipment	5 825	12 235	5 825	12 235
Total capital commitments				
Already contracted for but not provided for	205 348	78 387	205 348	78 387
Not yet contracted for and approved	5 825	12 235	5 825	12 235
	211 173	**90 622**	**211 173**	**90 622**
Authorised operational expenditure				
Already contracted and approved				
• Current expenditure	1 938 019	1 933 128	1 938 019	1 933 128
Not yet contracted for and approved				
• Current expenditure	48 743	46 893	48 743	46 893
Total operational commitments				
Already contracted for approved	**1 938 019**	**1 933 128**	**1 938 019**	**1 933 128**

This committed expenditure will be financed by retained surpluses, existing cash resources and funds internally generated.

Operating leases - as lessee (expense)				
Minimum lease payments due				
- within one year	10 297	17 282	10 297	17 282
- in second to fifth year inclusive	1 698	14 555	1 698	14 555
	11 995	**31 837**	**11 995**	**31 837**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	'000	'000	'000	'000

32. Commitment (continued)

Operating lease payments represent rentals payable by the economic entity for certain of its office equipment. Leases are negotiated for an average term of five years and rentals are fixed for an average of three years. No contingent rent is payable.

33. Contingencies

Claims lodged for damages:				
WSU salaries dispute	15 309	15 309	15 309	15 309
605 Consulting matter	17 383	17 383	17 383	17 383
Drive Control Corporation matter	37 505	37 505	37 505	37 505
Ms B Mnguni	4 800	4 800	4 800	4 800
Mr W.P. Msimanga	3 000	3 000	3 000	3 000
Ms S. Fortuin	328	328	328	328
Diana Mabaso Incorporated	235	235	235	235
South African Medical Association on behalf of Dr Z. Moorad and Dr A. Jali	178	178	178	178
Rapid IT Solution	3 737	-	3 737	-
Chien	3 245	-	3 245	-
Sthathu / SKG	2 396	-	2 396	-
	88 116	**78 738**	**88 116**	**78 738**

The WSU has claimed that the salaries of HODs, Medical Scientists and Technologists are owed by the NHLS for the period 2007 - 2013. The amount is disputed by the NHLS as the staff for which the claim is being made are not the employees of the NHLS

There is a matter between 605 Consulting and NHLS, where the NHLS is being sued for an amount of R17.4 million as a result of an Alleged Breach of Contract.

There is another matter between Drive Control and the NHLS, where the NHLS is being sued for an amount of R37.5 million as a result of an Alleged Breach of Contract.

There is also another matter between Ms B Mnguni and the NHLS, where the NHLS is being sued for personal injury against the NHLS which amount to R4.8 million.

There is also another labour matter between Mr W P Msimanga and the NHLS, where the NHLS is being sued for an amount of R3.0 million due to a Labour matter.

There is also another matter between Mr S Fortuin and the NHLS, where the NHLS is being sued for personal injury against the NHLS which amounts to R0.3 million.

There is also another matter between Diana Mabaso Inc and the NHLS, where the NHLS is being sued for damages for legal fees by the law firm which amounts to R0.2 million.

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	'000	'000	'000	'000

33. Contingencie (continued)

The NHLS has not concluded wage negotiations with regards to the annual salary adjustment for the 2020/21 financial period for NHLS employees whom are eligible for the a salary adjustment. The matter is dependent on multiple factors which have not been finalised at the date of publishing the NHLS annual financial statement. This matter is of the highest priority to the NHLS and is receiving the necessary attention from the NHLS board and the NHLS executive management.

Contingent assets

Mariana Madfaslina Lloyd Jansen Van Vuurent	1 630	-	1 630	-

There is a matter between the NHLS and Mariana Madfaslina Lloyd Jansen Van Vuuren where the NHLS is claiming the amount of R1.6 million from an ex employee as a result of breach of penalty.

34. Related parties

Relationships

Board Members	Prof Eric Buch
	Prof Jeffrey Mphahlele Dr Lesley Bamford Mr Ben Durham Dr Gerhard Goosen Prof Mpho Klaas Kgomo Mr Jonathan Mallett Prof Thanyani Jonas Mariba Dr Siseko Martin Ms Sphiwe Mayinga Dr Balekile Edward Mzangwa Mr Koena Joseph Nkoko Dr Naledzani Ramalivhana Prof Mary Hazel Ross Mr Michael Sachs Mr Michael Shingange Mr Ian van der Merwe Ms Nicolene Van der Westhuizen
Controlling entity	National Department of Health
Controlled Entity	South African Vaccine Producers (Pty)
Provincial Departments	Eastern Cape Department of Health Gauteng Department of Health Limpopo Department of Health North West Department of Health KwaZulu-Natal Department of Health Western Cape Department of Health Northern Cape Department of Health Mpumalanga Department of Health Free State Department of Health

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	'000	'000	'000	'000

34. Related parties (continued)

Universities	University of Cape Town University of Stellenbosch University of Western Cape University of Free State University of Witwatersrand University of Pretoria Sefako Makgatho Health Sciences University University of Limpopo University of KwaZulu-Natal Walter Sisulu University
Members of key management	Dr K. Chetty (Chief Executive Officer) Mr M.J. Shai (Acting Chief Financial Officer) Adv M.M. Mphelo (Company Secretary) Mr S.T. Hlongwane (Chief Information Officer) Dr S.M. Kgalamono (NIOH Director) Prof K.P. Mlisana (AARQA Executive) Prof L. Morris (Interim NICD Director) Mr J.B. Mofokeng (Acting Executive: Human Resources) Ms M. Saffer (SAVP Director) Prof A.J. Puren (Interim NICD Director)

Related party balances				
Amounts included in Trade receivable regarding related parties				
By Region				
Eastern Cape	667 200	479 406	667 200	479 406
Free State	162 611	79 066	162 611	79 066
Gauteng	704 444	1 048 244	704 444	1 048 244
KwaZulu-Natal	2 396 530	2 341 029	2 396 530	2 341 029
Limpopo	40 103	44 465	40 103	44 465
Mpumalanga	79 848	23 753	79 848	23 753
North West	211 741	179 384	211 741	179 384
Northern Cape	193 642	100 880	193 642	100 880
Western Cape	59 604	35 318	59 604	35 318
	4 515 723	**4 331 545**	**4 515 723**	**4 331 545**
Provision for doubtful debts related to outstanding balances with related parties				
By Region				
Gauteng	165 809	401 552	165 809	401 552
KwaZulu-Natal	2 575 051	2 585 016	2 575 051	2 585 016
	2 740 860	**2 986 568**	**2 740 860**	**2 986 568**
Amounts in Trade receivables regarding related parties				
By Segment				
Anti-retrovial programmes	384 455	325 060	384 455	325 060
Correctional Services	6 879	7 389	6 879	7 389
Defence	6 319	4 308	6 319	4 308
Health Clinics	1 400 150	1 078 069	1 400 150	1 078 069
Hospitals	2 714 851	2 912 286	2 714 851	2 912 286

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	'000	'000	'000	'000
34. Related parties (continued)				
Municipalities	1 843	3 961	1 843	3 961
Other Public Entities	1 226	(8 568)	1 226	(8 568)
Universities		9 040		9 040
	4 515 723	**4 331 545**	**4 515 723**	**4 331 545**
Amounts included in Trade Payables regarding related parties				
By Region				
Eastern Cape	73	-	73	-
Free State	38	33	38	33
Gauteng	3 329	7 193	3 329	7 193
KwaZulu-Natal	252	53	252	53
Limpopo	98	102	98	102
North West	462	462	462	462
Western Cape	949	1 450	949	1 450
	5 201	**9 293**	**5 201**	**9 293**
Amounts included in Trade Payables regarding elated parties				
By Segment				
Contract Laboratory Services	16	15	15	16
Municipalities	3 355	7 307	3 355	7 307
National Public Entities	681	508	681	508
Provincial Public Entities	33	12	33	12
Universitities	1 116	1 451	1 116	1 451
	5 201	**9 293**	**5 201**	**9 293**
Related party transactions				
Services billed to related parties				
By Region				
Eastern Cape	1 103 487	921 587	1 103 487	921 587
Free State	507 107	396 380	507 107	396 380
Gauteng	2 627 362	2 223 146	2 627 362	2 223 146
KwaZulu-Natal	2 514 243	2 222 328	2 514 243	2 222 328
Limpopo	532 565	527 115	532 565	527 115
Mpumalanga	619 624	534 730	619 624	534 730
National	-	35	-	35
North West	519 480	473 103	519 480	473 103
Northern Cape	227 116	159 448	227 116	159 448
Western Cape	1 057 085	880 647	1 057 085	880 647
	9 708 069	**8 338 519**	**9 708 069**	**8 338 519**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	'000	'000	'000	'000
Services billed to related parties By Segment				
Anti-retroviral	3 160 407	3 245 122	3 160 407	3 245 122
Correctional Services	35 335	26 889	35 335	26 889
Defence	32 268	34 066	32 268	34 066
Health Clinic	2 502 554	976 316	2 502 554	976 316
Hospitals	3 865 234	3 975 858	3 865 234	3 975 858
Municipalities	14 058	17 485	14 058	17 485
Other Public entities	13 674	14 221	13 674	14 221
Universities	84 539	48 562	84 539	48 562
	9 708 069	**8 338 519**	**9 708 069**	**8 338 519**
Purchases from related parties By Region				
Eastern Cape	2 940	2 892	2 940	2 892
Free State	7 493	10 438	7 493	10 438
Gauteng	91 726	75 075	91 726	75 075
KwaZulu-Natal	1 263	898	1 263	898
Limpopo	433	540	433	540
North West	512	520	512	520
Western Cape	32 207	31 351	32 207	31 351
	136 574	**121 714**	**136 574**	**121 714**
Purchases from related parties				
By Segment				
Contract Laboratory Services	32 516	17 364	32 516	17 364
Municipalities	49 202	46 394	49 202	46 394
National Public Entities	15 994	17 099	15 994	17 099
Provincial Public Entities	176	166	176	166
Universities	38 686	40 691	38 686	40 691
	136 574	**121 714**	**136 574**	**121 714**

Notes to the Audited Annual Financial Statements

35. Prescribed Officers and Board members' emoluments - R'000s

Emoluments were paid to the board members or any individuals holding a prescribed office during the year.

Prescribed Officers
2021

	Salaries	Retirement Contribution	Medical Contribution	Expense Allowance	Other**	Bonus	Total
	R'000	R'000	R'000	R'000	R'000	R'000	R'000
Dr K. Chetty (Chief Executive Officer)	2 384	209		39	25	-	2 657
Mr M. Sass (Chief Financial Officer)	2 007	182	71	30	24		2 314
Mr M.J. Shai (Acting Chief Financial Officer from 01 January 2021)	492		-	-	6	-	498
Adv M. Mphelo (Company Secretary)	1 863	163	-	-	22	-	2 048
Mr S.T. Hlongwane (Chief Information Officer)	1 701	158	107	-	20	-	1 986
Dr S.M. Kgalamono (NIOH Director)	1 790	194	122	65	23	-	2 194
Prof K.P. Mlisana (AARQA Executive)	2 044	191	143	3	25		2 406
Prof L. Morris (Interim NICD Director up to 31 December 2020)	1 606	186	39	1	20	13	1 865
Dr M. Mosia (Past Executive: Human Resources)	288	27	13	10	7		345
Mr J. Mofokeng (Acting Executive: Human Resources from 01 November 2020)	648	50	-	23	8	-	729
M. Saffer (SAVP Director)	624	55	-	2	9	-	690
Prof A.J. Puren (Interim NICD Director from 01 January 2021)	534	51	29	3	7	-	624
	15 981	**1 466**	**524**	**176**	**196**	**13**	**18 356**

Notes to the Audited Annual Financial Statements

35. Prescribed Officers and Board members' emoluments - R'000s (continued)

2020

	Salaries	Retirement contribution	Medical contribution	Expense Allowance	Other**	Bonus	Leave paid out	Total
	R'000	R'000	R'000	R'000	R'000	R'000	R'000	R'000
Dr K. Chetty (Chief Executive Officer)	2 155	189		38	20			2 402
J. Mogale (Past Chief Executive Officer)	225	18			7		454	704
M. Sass (Acting Financial Officer)	1 783	61	18		19			1 881
S.S. Zulu (Past Chief Financial Officer)	182				5		317	504
Adv M.M Mphelo (Company Secretary)	1 849	162		6	20			2 037
S.T Hlongwane (Chief Information Officer)	425	40	27		4			496
M. Nkosi (Acting Chief Information Officer up to 31 December 2019	925	72	41	6	11			1 055
Dr S.M. Kgalamono (Acting Executive: NIOH)	1 788	186	129	91	21			2 215
Prof K.P. Mlisana (AARQA Executive)	2 054	191	133	30	23			2 431
Prof L. Morris (Interim NICD Director)	1 744	201	37	2	19	13		2 016
Dr M. Mosia (Executive: Human Resources)	1 718	162	71	60	55			2 066
M. Saffer (SAVP Director)	832	73		4	10			919
	15 680	**1 355**	**456**	**237**	**214**	**13**	**771**	**18 726**

** Other payments include company contributions for skills development, UIF, expense recoveries and long service awards.

Service contract

Prescribed Officers are subject to written employment agreements. The employment agreements regulate duties, remuneration, allowances, restraints, leave and notice periods of these executives. None of these service contracts exceed five years

Notes to the Audited Annual Financial Statements

35. Prescribed Officers and Board members' emoluments - R'000s (continued)

Non-executive board members

2021

	Member's fees	Committees fees	Total
	R'000	R'000	R'000
Dr B.E. Mzangwa	-	6	6
Prof E. Buch	112	-	112
Prof T.J. Mariba	148	-	148
Dr S. Martin	71	-	71
Ms S Mayinga	132	-	132
Prof M. Ross	137	-	137
Mr M. Shingange	91	-	91
Mr M. Sachs	67	-	67
	758	**6**	**764**

2020

	Member's fees	Other fees (Constantly fees to subsidiary)	Total
	R'000	R'000	R'000
Dr B.E. Mzangwa	10	18	28
Prof E. Buch	311	-	311
Dr G. Goosen	-	12	12
Prof M. Ross	149	4	153
Mr M. Shingange	55	3	58
Ms N. Mkhize	-	27	27
Prof C.L. Obi	209	21	230
Ms S. Mayinga	142	4	146
Dr T. Tucker	88	-	88
Dr Z.A. Mavuso	93	4	97
	1 057	**93**	**1 150**

*Other fees relate to travel re-imbursement, out-of-pocket expenses and other company contributions.

Notes to the Audited Annual Financial Statements

36. Risk management

Financial risk management

The economic entity's activities expose it to a variety of financial risks: market risk (including currency risk, fair value interest rate risk, cash flow interest rate risk and price risk), credit risk and liquidity risk.

The economic entity's overall risk management program focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the economic entity's financial performance. Risk management is carried out by a central treasury department under policies approved by the accounting authority. Economic Entity treasury identifies and evaluates financial risks in close co-operation with the economic entity's operating units. The accounting authority provides written principles for overall risk management, as well as written policies covering specific areas, such as interest rate risk, credit risk, and investment of excess liquidity.

Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash and the availability of funding through an adequate amount of committed credit facilities and the ability to close out market positions. Due to the dynamic nature of the underlying businesses, economic entity treasury maintains flexibility in funding by maintaining availability of funds under short-term investments. At year end the investment in short-term deposits amounted to R2.9bn (2020: R3.7bn).

The economic entity's risk to liquidity is a result of the funds available to cover future commitments. The economic entity manages liquidity risk through an ongoing review of future commitments and credit facilities.

The table below analyses the economic entity's financial liabilities into relevant maturity groupings based on the remaining period at the statement of financial position to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows. Balances due within 12 months equal their carrying balances as the impact of discounting is not significant.

	R'000	R'000
Economic entity		
At 31 March 2021		
	Less than 1 year	**Between 1 and 2 years**
Payables from exchange transactions	1 140 172	-
Other financial liabilites	4 920	-
Finance lease obligation	18 727	102
At 31 March 2020		
	Less than 1 year	**Between 1 and 2 years**
Payables from exchange transactions	725 876	-
Other financial liabilities	4 824	5 056
Finance lease obligation	18 148	18 982
Controlling entity		
At 31 March 2021		
	Less than 1 year	**Between 1 and 2 years**
Payables from exchange transactions	1 139 133	-
Other financial liabilites	4 920	-
Finance lease obligation	18 727	102
At 31 March 2020		
	Less than 1 year	**Between 1 and 2 years**
Payables from exchange transaction	723 277	-
Other financial liabilities	4 824	5 056
Finance lease obligation	18 148	18 982

Credit risk

Credit risk consists mainly of cash deposits, cash equivalents, and trade debtors. The entity only deposits cash with major banks with high quality credit standing and limits exposure to any one counter-party.

Notes to the Audited Annual Financial Statements

36. Risk management (continued)

Concentrations of credit risk with respect to trade receivables are limited due to the majority of receivables being owned by government departments. However, due to the current payment disputes with the KwaZulu-Natal Provincial Department of Health and Gauteng Department of Health, a total doubtful debt allowance of R2.741bn (2020: R2.987bn) has been raised for these Departments. Trade receivables are interest bearing and are generally on 30 day payment terms. All interest on overdue debt has been provided for in full due to various communications received from the relevant government departments indicating they will not be in a position to honour the the additional interest owed to NHLS.

Market risk

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000
37. Irregular expenditure				
Opening balance as previously reported	2 205 382	5 132 144	2 205 382	5 132 144
Correction of prior period error	(178 394)	(21 965)	(178 394)	(21 965)
Opening balance as restated	**2 026 988**	**5 110 179**	**2 026 988**	**5 110 179**
Add: Irregular Expenditure - current	778 639	776 388	778 639	776 388
Less: Amount condoned	-	(3 681 185)	-	(3 681 185)
Closing balance	**2 805 627**	**2 205 382**	**2 805 627**	**2 205 382**
Analysis of awaiting condonation per age classification				
Current year	778 639	776 388	778 639	776 388
Prior years	2 026 988	1 428 994	2 026 988	1 428 994

2 805 627	2 205 382	2 805 627	2 205 382

Notes to the Audited Annual Financial Statements

Figures in Rand

37. Irregular expenditure (continued)

Incidents/cases identified in the current year include those listed below:

		Economic entity		Controlling entity	
		2021	2020	2021	2020
		R'000	R'000	R'000	R'000
	Current Status				
Expired contracts	There is one contract that was under litigation but we have subsequently appointed a new provider. With regards to all other expired contracts there is currently a tender process being undertaken.	254 902	598 757	254 902	598 757
Contract overspend	This relates to one contract for which we have received bids for evaluation.	35 978		35 978	
No tender procedures	The NHLS is an ongoing process of issuing tenders and quotations to procure the items under this category.	315 016	168 399	315 016	168 399
Other non compliance	An investigation is currently ongoing to determine if any discliplinary action needs to be taken.	172 743	8 984	172 743	8 984
Fraudulent transaction	There is an ongoing investigation.	-	248	-	248
		778 639	**776 388**	**778 639**	**776 388**
Correction of prior period error					
Regular expenditure included in expired contracts and no tender procedures followed		(84 215)	-	(84 215)	-
Valid contracts included in expired contracts		(111 486)	-	(111 468)	-
Contract value exceeded		17 307	-	17 307	-
		(178 394)	**-**	**(178 376)**	**-**

Notes to the Audited Annual Financial Statements

		Economic entity		Controlling entity	
		2021	2020	2021	2020
		R'000	R'000	R'000	R'000

Figures in Rand

37. Irregular expenditure (continued)

Amounts condoned

The following amounts have been condoned:

	Condoned by (Condoning authority)				
Expired contracts	National Treasury	-	264 041	-	264 041
Contracts that exceeded Delegation of Authority	National Treasury	-	86 191	-	86 191
No tender procedures followed	National Treasury	-	1 744 381	-	1 744 381
Contract overspend	National Treasury	-	962 127	-	962 127
Contract not signed	National Treasury	-	140 009	-	140 009
Expenditure before contract	National Treasury	-	484 436	-	484 436
		-	**3 681 185**	**-**	**3 681 185**

Notes to the Audited Annual Financial Statements

	Economic entity		Controlling entity	
	2021	2020	2021	2020
	R'000	R'000	R'000	R'000

37. Irregular expenditure (continued)

Amounts condoned

Condoned by (Condoning Authority)

National Treasury	-	3 681 185	-	3 681 185

Overpayment

The NHLS procured certain PPE items at prices in excess of the prices regarded by the National Treasury as market related. These items included sanitisers, gloves and disposable plastic aprons. This was mainly due to local and global demand and supply challenges due to the COVID-19 pandemic. In instances where the price paid for PPE was regarded by the NHLS as excessive, the NHLS had initiated its own investigations and had also reported the relevant companies to the Competition Commission. Between 14 March and 30 July 2020, the NHLS placed 175 orders to the value of R 993 843 884 for PPE. Twenty-one purchase orders were selected for detail auditing by the Auditors. For 11 of these purchase orders, PPE were procured in excess of the maximum prices prescribed by the National Treasury. The total amount in excess of the prescribed maximum prices was R55 684 000 of which R 36 610 000 has already been disclosed as irregular expenditure. As at reporting date, the full extent of the overpayment is still being investigated. These investigations may result in additional irregular expenditure but the nature and extent at reporting date have not been established.

Matters under Assessment

At the time of reporting for the 2020/21 financial year, there were matters under assessment in line with the Irregular Expenditure Framework as published by the National Treasury. Assessment in this regard refers to test as assigned by the Accounting Authority/ Accounting Officer of NHLS, to identify possible irregularities in transactions processed and to confirm the allegations of irregular expenditure. This assessment is conducted in line with Instruction Notes issued by the National Treasury pertaining to Emergency Procurement in response to National State Disaster. These assessments may result in additional irregular expenditure but the nature and extent at reporting date have not been established.

Matters confirmed for COVID-19 Emergency Procurement

Irregular expenditure to the amount of R 172 742 175 has been confirmed for the 2020/21. This expenditure relates to procurement not in line with Instruction Notes issued by the National Treasury pertaining to Emergency Procurement in response to National State of Disaster. External and internal investigations are continuing. These investigations may result in additional irregular expenditure but the nature and extent at reporting date have not been established.

38. Prior-year adjustments

Presented below are those items contained in the statement of financial position and statement of financial performance that have been affected by prior-year adjustments, change in accounting policy and reclassifications:

Statement of financial position
Economic Entity 2020

	Note	As previously reported	Correction of error	Re-classification	Restated
Inventories [1]	3	173 577	(7 455)	-	166 122
Receivables from exchange transactions [2.1]	4	1 093 533	-	172 145	1 265 678
Receivables from non exchange transactions [3]	5	414 094	36 151	-	450 245
Payables from exchange transactions [2.1]&[2.2]	13	(555 237)	1 506	(172 145)	(725 876)
Share capital / contributed capital [4]		(332)	332	-	-
Accumulated surplus		(3 749 997)	(30 534)	-	(3 780 531)
		(2 624 362)	**-**	**-**	**(2 624 362)**

Notes to the Audited Annual Financial Statements

38. Prior-year adjustments (continued)

Controlling entity - 2020

	Note	As previously reported	Correction of error	Re-classification	Restated
		R'000	R'000	R'000	R'000
Inventories [1]	3	167 757	(7 455)	-	160 302
Receivables from exchange transactions [2.1]	4	1 091 571	-	172 145	1 263 716
Receivables from non exchange transactions [3]	5	414 094	36 151	-	450 245
Payables from exchange transactions [2.1]&[2.2]	13	(551 132)	-	(172 145)	(723 277)
Share capital / contributed capital [4]		(332)	332	-	-
Accumulated surplus		(3 735 547)	(29 028)	-	(3 764 575)
		(2 613 589)	**-**	**-**	**(2 613 589)**

[1] During the year it was noted that inventory that was used in the 2019/20 financial year was not expensed to Cost of Sales in the Statement of Financial performance.

[2.1] During the year there was a change in classificaiton for Debtors with credit balances from Receivables from exchange transactions to Payables from exchange transactions. The impact of the reclassition resulted in an increase in Receivables from exchange transactions and an increase in Payables from exchange transactions.

[2.2] During the year it was noted that there was an adjustment required on Payables from exchange transactions.

[3] During the year it was noted that there was an adjustment required on Receivables from non-exchange transactions.

[4] During the year it was noted that the Share Capital needs to be written off as the NHLS does not have any share certificates.

Economic entity - 2019

	Note	As previously reported	Correction of error	Re-classification	Restated
Receivables from exchange transactions [2.1]		1 838 465	-	154 633	1 993 098
Receivables from non exchange transactions [3]		431 468	36 151	-	467 619
Payables from exchange transactions [2.1]&[2.2]		(547 233)	1 638	(154 633)	(700 228)
Share capital / contributed capital [4]		(332)	332	-	-
Accumulated surplus		(2 667 775)	(38 121)	-	(2 705 896)
		(945 407)	**-**	**-**	**(945 407)**

Controlling entity - 2019

	Note	As previously reported	Correction of error	Re-classification	Restated
Receivables from exchange transactions [2.1]	4	1 835 991	-	154 633	1 990 624
Receivables from non exchange transactions [3]	5	431 468	36 151	-	467 619
Payables from exchange transactions [2.1]	13	(547 233)	-	(154 633)	(701 866)
Share capital / contributed capital [4]		(332)	332	-	-
Accumulated surplus		(2 652 607)	(36 483)	-	(2 689 090)
		(932 713)	**-**	**-**	**(932 713)**

Notes to the Audited Annual Financial Statements

38. Prior-year adjustments (continued)

Statement of financial performance
Economic entity - 2020

	Note	As previously reported	Correction of error	Restated
		R'000	R'000	R'000
Cost of Sales [1]&[2.2]	19	7 357 448	7 555	7 365 003
Expenditure [2.2]	26	1 300 400	32	1 300 432
Surplus for the year		**8 657 848**	**7 587**	**8 665 435**

The correction of error above resulted in the surplus for the year being restated from R1 082 222 to R1 074 635.

Controlling entity - 2020

	Notes	As previously reported	Correction of error	Restated
Cost of Sales [1]	19	7 332 094	7 455	7 339 549

The correction of error above resulted in the surplus for the year being restated from R1 082 940 to R1 075 485.

39. Segment information

General information

Identification of segments

The conomic entity is organised and reports to management on the basis of nine major provinces withing the country. The segments were organised around the the target market. Management uses these same segments for determining strategic objectives. Segments were aggregated for reporting purposes.

Information reported about these segments is used by management as a basis for evaluating the segments' performances and for making decisions about the allocation of resources. The disclosure of information about these segments is also considered appropriate for external reporting purposes.

Types services by segment

All the segments within the economic entity offer similar services namely laboratory testing, teaching and research services.

Notes to the Audited Annual Financial Statements

Figures in Rand

39. Segment information (continued)

Segment surplus or deficit, assets and liabilities

Economic entity - 2021

	Laboratory Service	NIOH	NICD	SAVP	Total
	R'000	R'000	R'000	R'000	R'000
Revenue					
Revenue from non-exchange transactions	311 254	109 635	434 695	-	855 584
Revenue from exchange transactions	9 740 616	20 377	34 354	25 642	9 820 989
Other income	1 005 657	17 184	83	-	1 022 924
Interest received	134 263	6 206	22 717	519	163 705
Fair Value adjustment	-	-	-	15	15
Total segment revenue	11 191 790	153 402	491 849	26 176	11 863 217
Entity's revenue					11 863 217
Expenditure					
Cost of sales	9 998 121	120 057	321 670	22 923	10 462 771
Operating expense	1 164 417	10 458	63 829	2 461	1 241 165
Depreciation and amortisation	82 390	5 218	13 371	(184)	100 795
Interet paid	3 348	141	208	-	3 697
Taxation	-	-	-	480	480
Total segment expenditure	**11 248 276**	**135 874**	**399 078**	**25 680**	**11 808 908**
Total segmental surplus					**54 309**

Notes to the Audited Annual Financial Statements

Figures in Rand

39 Segment information (continued)

Economic entity - 2021

	Laboratory Service	NIOH	NICD	SAVP	Total
	R'000	R'000	R'000	R'000	R'000
Revenue					
Revenue from non-exchange transaction	312 975	112 666	359 865	-	785 506
Revenue from exchange transactions	8 396 098	14 242	25 702	29 117	8 465 159
Other income	177 860	2 439	381	1	180 681
Interest received	276 874	8 468	29 870	629	315 841
Total segment revenue	**9 163 807**	**137 815**	**415 818**	**29 747**	**9 747 187**
Entity's revenue					**9 747 187**
Expenditure					
Cost of sales	6 738 733	117 406	340 668	25 177	7 214 530
Operating expenses	1 225 914	13 664	56 264	2 519	1 296 851
Depreciation and amortisation	112 348	6 704	25 610	229	144 894
Fair value adjustments	-	-	-	23	23
Interest expense	5 641	190	322	125	6 278
Taxation	-	-	-	816	816
Total segment expenditure	**8 082 636**	**137 964**	**422 864**	**29 021**	**8 672 485**
Total segmental surplus					**1 074 702**

Notes to the Audited Annual Financial Statements

Economic entity		Controlling entity	
2021	2020	2021	2020
R'000	R'000	R'000	R'000

39. Segment information (continued)

Measurement of segment surplus or deficit assets and liabilities Basis of accounting for transactions between reportable segments

The accounting policies of the segments are the same as those described in the summary of significant accounting policies.

40. Budget differences

Material differences between budget and actual amounts

The budget was prepared on an accruals basis covering the financial year ended 31 March 2021 The variances between budget and actual which are numerically 10% and R100m above or below budget are explained below:

40.1. Rendering of services

The variance is caused by unanticipated change in the sales mix driven mainly test volumes of COVID-19 than the levels anticipated during the budget period.

40.2. Internal Recoveries

The increase in recoveries was caused by the write offf of the Utilities Provision.

40.3. Grant Income

No amounts were budgeted for grant income.

40.4. Public contributions and donations

This is due to funding from the Solidarity Fund to assist the NHLS in its response to the COVID-19 pandemicn.

40.5. General Expenses

The expenditure has been driven by COVID-19 expenditure.

41. Change in estimate property plant and equipment

The useful life of certain assets that were fully depreciated were adjusted by one to three years. The effect of this revision has increased the depreciation charges for the current and future periods by R49,1 million for the Controlling entity and R49,3 million for the Economic Entity.

42. Fruitless and wasteful expenditure

Opening balance as previously reported	9	-	-	-
Opening balance as restated	**9**	**-**	**-**	**-**
Add: Expenditure identified - current	207	9	-	-
Closing balance	**216**	**9**	**-**	**-**

Notes to the Audited Annual Financial Statements

43. Covid-19 Virus Donations

NHLS received the following donations in relation to the COVID-19 pandemic:

Donor Name	Items donated	2021 R'000	2020 R'000
ABSA Africa	Mobile laboratory and vehicles	5 100	-
Africa CDC	Reagents testing kit	-	-
African Union -	PPE / Reagents/ Ventilators	-	--
Anglo American	Laboratory Equipment	-	-
Chai	Laboratory Consumables	-	-
Chinese Government	Reagents and Laboratory Equipment	1 956	-
Dept of Agriculture	Laboratory Equipment	1 400	-
Department of Water and Sanitation	PPE	2	-
Department of Health - (WC)	Laboratory Consumable	80	-
Ford SA	Surveillance Support	2 500	-
Gift of the givers		-	42
Google SA	Mobile laboratory and vehicles	-	-
International Atomic Energy Agency	PPE/Reagents/Laboratory Consumables	-	-
Jack Ma foundation		-	-
Kingdom Netherlands	Reagents	-	-
Orlando Pirates/Kaizer Chiefs and Multichoice		-	19 742
Right to Care		-	374
Russian Consulate		-	-
Samsung Electronics (SA)	Reagents	2	-
Sasol	Mobile Laboratory Vehicles (Fuel)	241	-
Sasol Foundation	Mobile Laboratory Vehicles	-	-
Solidarity Fund	Reagents	250 869	-
The Department of Foreign Affairs (Canada)	Laboratory Equipment	-	-
The Foundation for Professional Development (Germany)	Laboratory Equipment	10 745	-
The People's Republic of China	Reagents	-	-
Total SA	Mobile Laboratory Vehicles (Fuel)	9 000	-
UNICEF	Reagents/Laboratory Consumables	460	-
US Defense Threat Reduction Agency	Laboratory Equipment	-	-
Volkswagen SA	Laboratory Office and Compute Equipment	4 000	-
World Health Organization	Reagents/Laboratory Consumables	11 536	
		297 891	**20 158**

The amounts shown above from the donors are in South African Rands and the monetory value is per NHLS supplier pricing. Where no amount is shown the price is unknown.

Detailed Statement of Financial Performance

	Note(s)	Economic entity		Controlling entity	
		2021	2020 Restated*	2021	2020 Restated*
		R'000	R'000	R'000	R'000
Revenue					
Sale of goods		25 642	29 117	-	-
Rendering of service		9 752 964	8 428 133	9 752 964	8 428 133
Miscellaneous other revenue		42 383	7 909	42 383	7 909
Government grants and subsidies		855 584	785 506	855 584	785 506
		10 676 573	**9 250 665**	**10 650 931**	**9 221 548**
Cost of sales	19	**(10 571 881)**	**(7 365 003)**	**(10 549 259)**	**(7 339 549)**
Gross surplus		**104 692**	**1 885 662**	**101 672**	**1 881 999**
Other income					
Fees earned		2 284	970	2 284	970
Royalties received		2 063	4 407	2 063	4 407
Discount received		305	608	305	607
Recoveries		502 922	7	502 922	7
Teaching Income		87 532	63 761	87 532	63 761
Sundry Income		826	3 444	826	3 444
Grant income recognised		176 123	102 880	176 123	102 880
Interest received	22	163 705	315 841	163 186	315 212
Public contributions and donations		250 869	4 604	250 869	4 604
		1 186 629	**496 522**	**1 186 110**	**495 892**
Expenses (Refer to page 78)		**(1 232 850)**	**(1 300 432)**	**(1 239 574)**	**(1 296 253)**
Operating surplus	21	**58 471**	**1 081 752**	**58 857**	**1 081 638**
Interest expense	23	(3 697)	(6 278)	(3 697)	(6 153)
Fair value adjustments		15	(23)	-	-
		(3 682)	**(6 301)**	**(3 697)**	**(6 153)**
Surplus before taxation		**54 789**	**1 075 451**	**55 160**	**1 075 485**
Taxation	24	480	816	-	-
Surplus for the year		**54 309**	**1 074 635**	**55 160**	**1 075 485**

Detailed Statement of Financial Performance

	Note(s)	Economic entity		Controlling entity	
		2021	2020	2021	2020
			Restated*		Restated*
		R'000	R'000	R'000	R'000
Operating expenses (by function)					
Advertising		889	308	895	308
Archiving and Storage		8 497	6 498	8 497	6 498
Auditors remuneration	27	12 511	11 393	12 511	11 059
Bad debts written off		1 640	2 056	1 640	2 056
Bank charges		9 766	12 594	9 725	12 544
Cleaning		8 107	4 824	8 094	4 783
Computer expenses		2 415	1 049	2 414	1 049
Conferences and seminars		56	608	56	588
Consulting and professional fees		67 873	39 582	67 717	39 467
Consumables		18 335	16 646	18 303	16 638
Debt Impairment		32 654	241 871	30 559	239 543
Debt collection		952	1 013	952	1 013
Delivery expenses		2 817	1 040	2 806	1 037
Depreciation, amortisation and impairments		(8 315)	1 974	(8 429)	1 921
Discount allowed		35 674	20 642	35 674	20 642
Employee costs		299 341	286 038	298 476	285 628
Entertainment		2	21	2	21
Fines and penalties		(27)	2	(27)	2
Insurance		9 173	6 956	9 173	6 956
Lease rentals on operating lease		41 000	38 733	40 875	38 633
Legal expenses		20 494	17 343	20 492	17 322
Loss on disposal of assets		3 335	3 815	3 335	3 815
Loss on exchange difference		2 127	3 880	2 127	3 870
Minor assets		8 929	5 871	8 929	5 879
Motor vehicle expenses		11 093	563	11 093	563
Other contract expenses		-	563	-	563
Other expenses		907	1 173	917	1 017
Packaging		9 552	9 329	9 407	9 289
Petrol and oil		10 447	7 297	10 447	7 297
Printing and stationery		44 624	41 300	44 585	41 088
Postage and courier		329	133	329	133
Project Management expenses		690	101	690	101
Promotions		2	411	2	411
Promotions and sponsorships		38	37	38	37
Repairs and maintenance		48 442	55 733	48 412	55 719
Research Trust		5	26	5	26

Detailed Statement of Financial Performance

	Note(s)	Economic entity		Controlling entity	
		2021	2020	2021	2020
			Restated*		Restated*
		'000	'000	'000	'000
Royalties and license fees		1 582	3 329	1 582	3 329
Security		4 559	1 202	4 559	1 202
Software development expenses		15 546	6 373	15 546	6 373
Software expenses		176 177	132 039	176 177	132 039
Staff welfare		6 078	9 827	5 911	9 700
Subscriptions		4 763	579	4 740	540
Telephone and fax		124 541	88 054	124 459	87 949
Training		26 077	43 787	26 077	43 787
Travel - local		11 412	36 918	11 412	36 917
Travel - overseas		24	578	24	578
Utilities		157 717	136 323	157 717	136 323
		1 232 850	**1 300 432**	**1 228 925**	**1 296 253**

* See Note 38

The supplementary information presented does not form part of the audited group annual financial statements and is unaudited

NHLS COVID-19 Testing Laboratories

Province	No	Laboratory	Address	Type of test(s)
Eastern Cape	1.	Nelson Mandela Academic/Walter Sisulu University	Nelson Academic Hospital, Sisson Street, Fortgale, Umtata	PCR and Antigen
	2.	East London laboratory	Frere Hospital, 1 Amalinda Road, East London	PCR and Antigen
	3.	Cecilia Makiwane laboratory	Cecilia Makiwane Hospital Billie Road,Mdantsane	PCR and Antigen
	4.	Bisho	Bisho Hospital, Bisho	Antigen
	5.	Victoria	Victoria Hospital, Ntselamanzi Location, Alice	Antigen
	6.	SS Gida	SS Gida Hospital, Cata Street, Keiskammahoek	Antigen
	7.	Willowvale	Willowvale Health Centre, Willowvale	Antigen
	8.	Madwaleni	Madwaleni Hospital, Xhora Administrative Area, Elliotdale	Antigen
	9.	Butterworth	Butterworth Hospital, Scanlen Street, Butterworth	Antigen
	10.	Port Elizabeth Provincial laboratory	Corner of Buckingham and Eastbourne Road, Ground Floor, Mount Croix, Port Elizabeth	PCR and Antigen
	11.	Livingstone laboratory	Livingstone Hospital, Stanford Road, Korsten, Port Elizabeth	Antigen
	12.	Dora Nginza	Dora Nginza Hospital, Spondau Road, Zwide, Port Elizabeth	Antigen
	13.	Uitenhage	Uitenhage Provincial Hospital, Channer Street, Uitenhage	Antigen
	14.	Somerser East	Andries Vosloo Hospital, Charl Street, Somerset East	Antigen
	15.	Port Alfred	Kowie Hospital, Southwell Street, Port Alfred	Antigen
	16.	Graaff Reinet	Midlands Hospital, Albertyn Street, Graaff Reinet	Antigen
	17.	Grahamstown	Settlers Hospital, Milner Street, Grahamstown	Antigen
	18.	Cala	Cala Hospital, Druly Lane Street, Cala	Antigen
	19.	Canzibe	Canzibe Hospital, Mtata Road, Ngqeleni	Antigen
	20.	Cofimvaba	Cofimvaba Hospital, Zigudu Road, Cofimvaba	Antigen
	21.	Cradock	Provincial Hospital, Hospital Street, Cradock	Antigen
	22.	Glen Grey	Glen Grey Hospital, Lady Frere	Antigen
	23.	Hewu	Hewu Hospital, Whittlesea	Antigen
	24.	St Barnabas	St Barnabas Hospital, Libode	Antigen
	25.	Zitulele	Zitulele Hospital, Mqanduli	Antigen
	26.	Queenstown	Frontier Hospital, Kingsway, Queenstown	PCR and Antigen
	27.	All Saints	All Saints Hospital, Engcobo	Antigen
	28.	Isilimela	Isilimela Hospital, Port St Johns	Antigen
	29.	St Elizabeth	St Elizabeth Hospital, Lusikisiki	Antigen
	30.	St Patrick's	St Patrick's Hospital, Bizana	Antigen
	31.	Mount Ayliff	Mount Ayliff Hospital, Mount Ayliff	PCR and Antigen
	32.	Holy Cross	Holy Cross Hospital, Flagstaff	Antigen
	33.	Matatiele	Matatiele Hospital, Matatiele	PCR and Antigen
	34.	Mary Teresa	Mary Teresa Hospital, Mount Frere	Antigen
	35.	Greenville	Greenville Hospital, Bizana	Antigen
	36.	Nessie Knight	Nesie Knight Hospital, Qumbu, 5180 via Qumbu Health Centre Laboratory, Qumbu	Antigen
	37.	NHLS Mobile Laboratory	Qasha's Neck	

Province	No	Laboratory	Address	Type of test(s)
Free State	38.	Manapo laboratory	Mofumahadi Manapo, Mopeli Hospital, Mampoi Street, Phuthaditjaba	PCR
	39.	Pelonomi laboratory	Pelonomi Hospital, 121 Dr Belcher Road, Heidedal, Bloemfontein	PCR
	40.	Universitas Academic laboratory	Room 433, 2nd Floor, Block E, Francois Retief Building, University of the Free State, Bloemfontein	PCR
	41.	NHLS Mobile laboratory	Maseru Bridge Land Border	Antigen
	42.	NHLS Mobile laboratory	Ficksburg Land Border	Antigen
	43.	NHLS Mobile laboratory	Caledonspoort Land Border	Antigen
	44.	NHLS Mobile laboratory	Van Rooyensgate Land Border	Antigen
	45.	Braamfontein TB laboratory	National Health Laboratory Service, Corner De Korte and Hospital Street, Braamfontein	PCR and Antigen
Gauteng	46.	Carletonville laboratory	Carletonville Extension 10	PCR
	47.	Charlotte Maxeke Johannesburg Academic laboratory	NHLS, Charlotte Hospital, 7 York Road, Parktown	PCR
	48.	Chris Hani Baragwanath Academic laboratory	Chris Hani Hospital, Chris Hani Road, Zone 6, Diepkloof, Soweto	PCR
	49.	Dr George Mukhari laboratory	Sefako Makgatho Health Science University, Virology Laboratory	PCR
	50.	Dr Yusuf Dadoo laboratory	Cnr Hospital Road and Memorial Avenue, Krugersdorp	PCR
	51.	Helen Joseph laboratory	Helen Hoseph Hospital, 1 Perth Road, Auckland Park, Johannesburg	
	52.	Jubilee laboratory	Jubilee Hospital, 92 Jubilee Road, Temba Rural	PCR
	53.	Kopanong laboratory	Kopanong Hospital, 2 Cassino Road, Duncanville, Vereeniging	PCR
	54.	Tambo Memorial laboratory	Tambo Memorial Hospital, 39 Railway Street, Plantation, Boksburg	PCR and Antigen
	55.	Tembisa laboratory	Tembisa Hospital, Reverend R.T.J. Namane Dr. Hospital View, Tembisa	PCR
	56.	Thelle Mogoerane laboratory	Thelle Mogoerane Hospital, 12390 Nguza Street, Vosloorus	PCR
	57.	Tshwane Academic Division, University of Pretoria	Department of Medical Virology, Tshwane Academic Division, Institute of Pathology Building, 2nd Floor, Room K3-31, Corner Beatrix and Dr Savage Streets, Tshwane	PCR and Antigen
	58.	NHLS Mobile laboratory	OR Tambo International Airport, 1 Jones Road, Kempton Park, Gauteng	PCR and Antigen
	59.	NHLS Mobile Laboratory	Lanseria International Airport, Phelindaba Road, Lanseria, Gauteng	PCR and Antigen
KwaZulu-Natal	60.	Addington laboratory	Addington Hospital, 16 Erskine Terrace, South Beach, Durban	PCR
	61.	Addington mobile	Addington Hospital, 16 Erskine Terrace, South Beach, Durban	Antigen
	62.	Edendale laboratory	Edendale Hospital, 89 Selby Msimang Road, Plessislaer, Pietermaritzburg	PCR
	63.	Inkosi Albert Luthuli Central Academic laboratory – Virology	Inkosi Albert Luthuli Central Hospital, Vusi Mzimela Road, Mayville, Durban	PCR
	64.	Itshelejuba laboratory	Itshelejuba Hospital, Pongola, KZN	PCR
	65.	King Edward laboratory	King Edward Laboratory, Sydney Road, Umbilo, Durban	PCR
	66.	Madadeni laboratory	Madadeni Hospital, Madadeni Road, Newcastle	PCR
	67.	Ngwelezane laboratory	Ngwelezana Hospital, Thanduyise Drive, Kuleka, Empangeni	PCR
	68.	RK Khan laboratory	RK Khan Hospital, 336 R K Khan Cir, Westcliff, Chatsworth	PCR
	69.	St Apollinaris laboratory	St. Apollinaris Hospital, Centocow Road, Makholweni, Creighton	PCR
	70.	NHLS Mobile laboratory	King Shaka International Airport	Antigen
	71.	NHLS Mobile laboratory	Golela Land Border	Antigen
	72.	NHLS Mobile laboratory	Kosi Bay Land Border	Antigen
	73.	NHLS Mobile laboratory	Richards Bay	Antigen
	74.	NHLS Mobile laboratory	Durban Harbour	Antigen
	75.	NHLS Mobile laboratory	Sani Pass	Antigen
Limpopo	76.	Ellisras laboratory	Ellisras Hospital, Lephalale	PCR
	77.	Letaba laboratory	Letaba Hospital, Lydenburg Road (R36), Tzaneen	PCR
	78.	Mankweng Provincial laboratory	Mankweng Hospital, Oos Bos Road, Polokwane	PCR
	79.	Polokwane Provincial laboratory	Polokwane Provincial Hospital, Corner Dorp and Hospital Streets, Polokwane	PCR
	80.	NHLS Mobile laboratory	Beit Bridge Land Border	Antigen
	81.	NHLS Mobile laboratory	Polokwane International Airport	Antigen
	82.	NHLS Mobile laboratory	Grobersbridge Land Border	Antigen

Province	No	Laboratory	Address	Type of test(s)
Mpumalanga	83.	Ermelo laboratory	Ermelo Provincial Hospital, Joubert Street, Ermelo	PCR
	84.	Middleburg laboratory	Middleburg Hospital, Hospital Street, Middleburg	PCR
	85.	Rob Ferreira laboratory	Rob Ferreira Hospital, Corner Madiba Drive and Piet Retief Street, Nelspruit	PCR
	86.	Shongwe laboratory	Shongwe Mission Hospital, Jeppes Reef Road, Malelane District	PCR
	87.	Embhuleni laboratory	Embhuleni Provincial Hospital, Eestehoek	PCR
	88.	NHLS Mobile laboratory	Lebombo Land Border	Antigen
	89.	NHLS Mobile laboratory	Oshoek Land Border	Antigen
	90.	NHLS Mobile laboratory	Mahamba Land Border	Antigen
Mpumalanga	91.	NHLS Mobile laboratory	Mananga Land Border	Antigen
	92.	NHLS Mobile laboratory	Jeppes Reef Land Border	Antigen
North West	93.	Joe Morolong laboratory	Joe Morolong Memorial Hospital, Dr. Ruth Segomotsi Mompti District, Vryburg	PCR
	94.	Mafikeng laboratory	Mafikeng Provincial Hospital, Cnr Lichtenburg and Mareetsane Rd, Mafikeng	PCR and Antigen
	95.	Rustenburg laboratory	Job Shimankane Tababna Provincial Hospital, Cnr Bosch and Heystek Streets, Rustenburg	PCR
	96.	Tshepong laboratory	Tshepong Hospital, Benhi Olifant, Uraniaville Road, Klerksdorp	PCR
	97.	NHLS Mobile laboratory	Skilpadshek Land Border	Antigen
	98.	NHLS Mobile laboratory	Kopfontein Land Border	Antigen
	99.	NHLS Mobile laboratory	Ramatlabama Land Border	Antigen
Northern Cape	100.	De Aar laboratory	De Aar Hospital, Visset Street, De Aar	Antigen
	101.	Kimberley laboratory	Kimberley Hospital, Robert Mangaliso Sobukwe Hospital,143 DuToitspan Road, Kimberley	PCR and Antigen
	102.	Springbok laboratory	Springbok Hospital, Hospital Street, Doornpoort, Springbok	PCR and Antigen
	103.	Tshwaragano laboratory	Tshwaragano Hospital, Kuruman, Northern Cape	PCR and Antigen
	104.	Upington laboratory	Upington Hospital, Upington	PCR and Antigen
	105.	NHLS Mobile laboratory	Vioolsdrift Land Border	Antigen
	106.	NHLS Mobile laboratory	Nakop Land Border	Antigen
Western Cape	107.	Beaufort West Laboratory	Beaufort Hospital, Hospital Hill, Beaufort West	PCR and Antigen
	108.	Ceres Hospital Mobile	Ceres Hospital, Rivierkant Straat	Antigen
	109.	Delft Clinic Mobile	Delft Community Health Clinic, Cape Town	Antigen
	110.	George laboratory	George Hospital, King George Park, Corner Davidsons and Langenhoven Rd Heatherlands, George	PCR and Antigen
	111.	Greenpoint Complex	Greenpoint Complex, Old City Hospital Comlex, Block F, Covid Laboratory, Portswood Road, Greenpoint, Cape Town	PCR and Antigen
	112.	Groote Schuur Academic laboratory	Groote Schuur Hospital, C17 Anzio Road, Observatory, Cape Town	PCR and Antigen
	113.	Helderberg laboratory	Helderberg Hospital, Lourensford Road, Golden Acre, Cape Town	Antigen
	114.	Hermanus laboratory	Hermanus Hospital, Hospital Steet, Hermanus	Antigen
	115.	Karl Bremer laboratory	Karl Bremer Hospital, Frans Conradie Drive, Bellville West, Cape Town	PCR and Antigen
	116.	Khayelitsha laboratory	Khayelitsha District Hospital, Corner Walter Sisulu and Steve Biko Road, Khayelitsha, Cape Town	PCR and Antigen
	117.	Knysna laboratory	Knysna Hospital, Knysna	PCR and Antigen
	118.	Mitchels Plain laboratory	Mitchelles Plain Hospital, Berman Drive, Lentegeur, Cape Town	Antigen

Province	No	Laboratory	Address	Type of test(s)
Western Cape	119.	Mitchels Plain Community Health Centre Mobile	Mitchels Plain Community Health Clinic, Cape Town	Antigen
	120.	Mosselbay laboratory	Mosselbay Hospital, 1st Avenue, Mossel Bay Central, Mossel Bay	PCR and Antigen
	121.	Oudtshoorn laboratory	Ouudtshoorn Hospital, Park Road, Oudtshoorn	PCR and Antigen
	122.	Paarl laboratory	Paarl Provincial Hospital, 10 Hospital Street, Lemoenkloof, Paarl	PCR and Antigen
	123.	Red Cross Children's Hospital laboratory	Red Cross Children's Hospital, Klipfontein Road, Rondebosch, Cape Town	Antigen
	123.	Tygerberg Academic Hospital	Virology Laboratory, 8th Floor, Clinical Building, Faculty of Medicine and Health Sciences, Tygerberg Medical School, Tygerberg	PCR and Antigen
	124.	Vredendal laboratory	Vredendal Hosptial, Van Der Stel Street, Vredendal	Antigen
	125.	Vredenburg laboratory	Admin Block, Vredenburg Hospital, Voortrekker Road, Vredenburg	Antigen
	126.	Worcester laboratory	Worcester Hosptial, Murray Street, Worcester	PCR and Antigen
	127.	Wesfleur Hospital Mobile	Wesfleur Hospital, Wesfleur Circle, Atlantis, Cape Town	Antigen
	128.	NHLS Mobile laboratory	Cape Town International Airport	PCR and Antigen

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