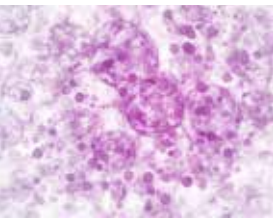
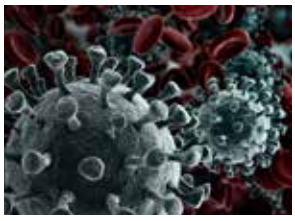
2021 2022

ANNUAL REPORT





NATIONAL HEALTH
LABORATORY SERVICE

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FINANCIAL HIGHLIGHTS (2021–2022)

The National Health Laboratory Service (NHLS) **maintained an unqualified audit opinion** with findings for the 2021/22 financial period.

The NHLS generated a **surplus** of **R76.4 million** for the financial year.

The total revenue for the NHLS **grew** from R10.5 billion **to R12.2 billion**.

Revenue from **COVID-19 testing** amounted to R2.4 billion, with **over 5 million tests** conducted.

The NHLS' total assets **increased** from a restated R7.4 billion in the prior year to **R7.8 billion** in the current year.

NON-FINANCIAL HIGHLIGHTS (2021–2022)

The NHLS **achieved 88%** of its set target compared to 86% in the previous financial year.

The NHLS had **18 new laboratories** accredited by SANAS as compared to 15 in the previous financial year.

The NHLS published **688 articles** in peer-reviewed journals as compared to 673 in the previous financial year.

The National Institute for Communicable Diseases (NICD) continued to play a pivotal role in ensuring prompt interventions regarding **communicable disease outbreaks** such as **COVID-19** in South Africa, by providing daily epidemiological updates to the National Department of Health (NDoH) without fail.

The NICD, in collaboration with other external stakeholders, was able to detect **SARS-CoV-2 RNAV ml** in **498** out of 548, **(91%) wastewater samples.**

The Institute is the **only entity in South Africa** that has obtained accreditation for **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.

In the period under review, **30 webinars** were conducted, with **over 11 225 participants** trained on **COVID-19 topics**. Cumulatively, this brings the total number of webinars conducted since the start of the pandemic in March 2020 to **98**, with **52 670 participants** trained.

The **Occupational Health and Safety Information System (OHASIS)** has proven to be an invaluable OHS management tool and continues to be adapted to cater to the new challenges posed by COVID-19, and the unique needs posed by the laboratory environment within the NHLS.

PART A

GENERAL INFORMATION

GENERAL INFORMATION

Registered name of the public entity:	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

ABBREVIATIONS AND ACRONYMS

AAR	Academic Affairs and Research
AARMS	Academic Affairs and Research Management System
AARQA	Academic Affairs, Research and Quality Assurance
ACTG	AIDS Clinical Trials Group
AFP	Acute Flaccid Paralysis
AGSA	Auditor-General of South Africa
AIDS	Acquired Immune Deficiency Syndrome
AMA	Anti-mitochondrial antibody
AMARA	Times Media Annual Recruitment Awards
AMR	Antimicrobial Resistance
Anti-LKM-1	Anti-liver/kidney microsomal antibody
APCA	Anti-parietal cell antibody
APP	Annual performance plan
aPTT	Activated prothrombin
ARAOH	African Regional Association of Occupational Health
ARC	Audit and Risk Committee
ARL	Arbovirus Reference Laboratory
ARMS-PCR	Amplification refractory mutation system polymerase chain reaction
ART	Antiretroviral therapy
ARV	Antiretroviral
ASLM	African Society for Laboratory Medicine
ASMA	Anti-smooth muscle antibody
AST	Aspartate Transaminase
AUDA	Africa Union Development Agency
BA	Bilateral agreement
BLUC	Blood and Laboratory User Committee
BPA	Blanket purchase agreement
BRICS	Brazil, Russia, India, China and South Africa
CANSA	Cancer Association of South Africa
CAPRISA	Centre for the AIDS Programme of Research in South Africa
CC	Collaborating Centre
CCHF	Crimean-Congo haemorrhagic fever
CCMT	Comprehensive Care Management and Treatment
CCMI	Competition Commission Market Inquiry
CCPCP	Cervical Cancer Prevention and Control Policy
CD4	Cluster of differentiation 4
CDC	Centers 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
CHAI	Clinton Health Access Initiative
CHBAH	Chris Hani Baragwanath Academic Hospital
CHC	Community Healthcare Centre
CHE	Council on Higher Education
CHIVSTI	Centre for HIV and STI
CIPC	Companies and Intellectual Property Commission
CM	Cryptococcal Meningitis
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CMSA	Colleges of Medicine of South Africa
CMV	Cytomegalovirus

ABBREVIATIONS AND ACRONYMS (CONTINUED)

CNS	Central nervous system
COBIT	Control Objectives for Information and Related Technologies
COO	Chief Operations Officer
CPD	Continuing professional development
CPP	Comprehensive prevention package
CPUT	Cape Peninsula University of Technology
CQI	Continuous quality improvement
CrAg	Cryptococcal antigen
CRDM	Centre for Respiratory Diseases and Meningitis
CRE	Carbapenem-resistant Enterobacteriaceae
CROI	Conference on Retroviruses and Opportunistic Infections
CRP	C-reactive protein
CSF	Cerebrospinal fluid
CSIR	Council for Scientific and Industrial Research
CTB	Centre for Tuberculosis
CTIA	Cape Town International Airport
CU	Comprehensive university
CVD	Cardiovascular disease
CVI	Centre for Vaccine and Immunology
DAFF	Department of Agriculture, Forestry and Fisheries
DBS	Dried blood spot
DCS	Department of Correctional Services
DCST	District Clinical Support Team
DGGE	Denaturing gradient gel electrophoresis
DGM	Dr George Mukhari Hospital
DEL	Department of Employment and Labour
DMP	Diagnostic Media Products
DNA	Deoxyribonucleic acid
DoH	Department of Health
DPHSR	Division of Public Health Surveillance and Response
DRC	Democratic Republic of Congo
dst	Drug susceptibility testing
DST	Department of Science and Technology
DTG	Dolutegravir
DTM&H	Diploma in Tropical Medicine and Hygiene
EAP	Employee Assistance Programme
ECC	Expert Chair Committee
ECHO	Project Extension for Community Healthcare Outcomes
ECM	Enterprise content management
EDTA	Ethylenediaminetetraacetic acid
EE	Employment Equity
EFI	European Federation of Immunology
EGK	Electronic gatekeeping
EID	Early infant diagnosis
ELISA	Enzyme-linked immunosorbent assay
EOC	Emergency Operations Centre
EPTB	Extra-pulmonary tuberculosis
EQA	External quality assessment
ESBL	Extended-spectrum beta-lactamase
ESF	Education Service Fee
ERP	Enterprise resource planning
EQA	External quality assessment
ET	Ekurhuleni Tshwane

ABBREVIATIONS AND ACRONYMS (CONTINUED)

EU	European Union
EV	Enterovirus
EXCO	Executive Management Committee
FA	Fanconi anaemia
FinCom	Financial Committee
FBC	Full blood count
FDA	Food and Drug Administration
FETP	Field Epidemiology Training Programme
FIOH	Finnish Institute of Occupational Health
FinCom	Financial Committee
FIND	The Foundation for Innovative New Diagnostics
FIOH	Finnish Institute of Occupational Health
FISH	Fluorescence in situ hybridisation
FNA	Fine needle aspiration
FPD	Foundation for Professional Development
FSASP	Federation of South African Societies of Pathology
GAM	Global AIDS Monitoring
GC-MS	Gas chromatography-mass spectrometry
GDD	Global Diseases Detection
GDH	Glutamate dehydrogenase
GDoH	Gauteng Department of Health
GDSP	Global Data Services Platform
GEMP	Graduate entry medical programme
GERMS-SA	Group for Enteric, Respiratory and Meningeal Disease Surveillance in SA
GFO	Grant Finance Office
GIS	Geographic information system
GLASS	Global Antimicrobial Resistance Surveillance System
GOARN	Global Outbreak Alert and Response Network
GRAP	Generally Recognised Accounting Practice
GSEC	Governance and Social Ethics Committee
GSH	Groote Schuur Hospital
GXP	GeneXpert
HA	Haemophilia A
HAART	Highly active antiretroviral therapy
HBV	Hepatitis B virus
HBC	Hepatitis C virus
HCT	HIV counselling and testing
HCW	Healthcare workers
HEU	HIV-exposed uninfected
HHV	Human herpesvirus
HIVDR	HIV drug resistance
HIV	human immunodeficiency virus
HIV PCR	human immunodeficiency virus - Polymerase chain reaction
HIV VL	human immunodeficiency virus viral load
HLA	Human leucocyte antigen
hMPV	Human metapneumovirus
HoD	Head of Department
HPCSA	Health Professions Council of South Africa
HPRS	Health Patient Registration System
HPV	Human papillomavirus
HRP	Hospital Revitalisation Programme
HSS	Health systems strengthening
HTA	Health technology assessment

ABBREVIATIONS AND ACRONYMS (CONTINUED)

HVTN	HIV Vaccine Trials Network
IALCH	INkosi Albert Luthuli Central Hospital
IAPC	Institutional Academic Pathology Committees
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association (IATA)
ICOH	International Commission on Occupational Health
ICT	Information and communications technology
ICU	Intensive care unit
IEC	International Electrotechnical Commission
IHR	International Health Regulations
IKM	Information and Knowledge Management
ILDAC	Integrated laboratory data analysis for care
iLEAD	Innovation for Laboratory Engineered Accelerated Diagnostics
ILI	Influenza-like illness
ILO	International Labour Organization
IMD	Inherited metabolic disease
IMDRF	International Medical Devices Regulatory Forum
IMT	Incident Management team
INR	International normalized ratio
IP	Intellectual Property
IPC	Infection prevention and control
IPR	Intellectual property rights
IQC	Independent quality control
IRMA	Immunoradiometric assay
ISO	International Organization for Standardization
IT	Information technology
ITGC	Information Technology Governance Committee
ITIL	Information technology infrastructure library
IVD	In-vitro device
JEE	Joint External Evaluation
JSW	Johannesburg Sedibeng West Rand
KEH	King Edward VIII Hospital
King IV	King Code of Governance Principles (King IV).
KPA	Key performance area
KPI	Key performance indicators
KIDCRU	Children's Infectious Diseases Clinical Research Unit
LAB/IPC	Laboratory and Infection Prevention and Control LBC Liquid-based cytology
LAM	Lipoarabinomannan
LAN	Local area network
LFT	Liver function test
LIS	Laboratory Information System
LPA	Line probe assay
LSHTM	London School of Hygiene and Tropical Medicine
LTI	Laboratory for Issue Immunology
MAC	Ministerial Advisory Committee
MALDI-TOF	Matrix-Assisted Laser Desorption/Ionization
MBOD	Medical Bureau for Occupational Diseases
MCDS	Minimum Clinical Data Set
MCH	Maternal Child Health
MCWH	Maternal child women's health
MDO	Missed diagnostic opportunity
MDR	Multidrug-resistance
MDR-TB	Multidrug-resistant tuberculosis

ABBREVIATIONS AND ACRONYMS (CONTINUED)

MEC	Member of the Executive Council
MGIT AST	Mycobacterium Growth Indicator Tube-Antibiotic Susceptibility Test
MHSC	Mine Health and Safety Council
MIC	Minimum inhibitory concentration
MLPA	Multiplex ligation-dependent probe amplification
MMed	Master of Medicine
MMPA	Mine Medical Professionals Association
MOU	Maternity Outpatient Unit
MoU	Memorandum of understanding
MRC	Medical Research Council
MRSA	Methicillin-resistant Staphylococcus aureus
MSSA	Methicillin-susceptible Staphylococcus aureus
MTBC	Mycobacterium tuberculosis complex
MTB/RIF	Mycobacterium tuberculosis/rifampicin
NAAT	Nucleic acid amplification test
NAGI	National Advisory Group on Immunisation
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
NGO	Non-governmental organisation
NGS	Next-generation sequencing
NHA	National Health Act, no. 61 of 2003
NHI	National Health Insurance
NHLS	National Health Laboratory Service
NHRC	National Health Research Committee
NIAID	National Institute of Allergy and Infectious Diseases
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
NIPMO	National Intellectual Property Management Office
NMC	Notifiable medical condition
NMCSS	Notifiable Medical Conditions Surveillance System
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NPG	National Pathology Group
NPO	Non-profit organisation
NPP	National Priority Programmes
NPPU	National Priority Programmes Unit
NPR	National Priority Research
NQF	National Qualifications Framework
NRF	National Research Foundation
NTT	National task team
OECD	Organisation for Economic Co-operation and Development
OEHS	Occupational and Environmental Health and Safety
OHASIS	Occupational Health and Safety Information System
OHS	Occupational Health and Safety

ABBREVIATIONS AND ACRONYMS (CONTINUED)

O.P.D.	Outpatient Department
ORU	Outbreak Response Unit
OTT	Office of Technology Transfer
PAHWP	Pan African Harmonisation Working Party
PathRed	Pathology Research and Development
PBMC	Peripheral blood mononuclear cell
PCR	Polymerase chain reaction
PCT	Patent Cooperation Treaty
pct	procalcitonin
PEPFAR	United States President's Emergency Plan for AIDS Relief
PFGE	Pulsed-field gel electrophoresis
PFMA	Public Finance Management Act
PHC	Primary Health Care
PIVOTAL	Professional, vocational, technical and academic learning
PLG	Panleucogated
PLWHIV	People living with HIV
PMA	Prioritised management area
PMC	Peri-mining communities
PMS	Post-market Surveillance
PMTCT	Prevention of Mother-to-Child Transmission
POCT	Point-of-care testing
POPI	Protection of personal information
PP	Plasma preparation
PPC	Parliamentary Portfolio Committee
PPE	Personal Protective Equipment
PPO Serve	Professional Provider Organisation Services
PRF	Poliomyelitis Research Foundation
PSC	Plasma Separation Card
PTS	Proficiency testing schemes
PwC	PricewaterhouseCoopers Inc
QA	Quality Assurance
QAD	Quality Assurance Division
QC	Quality control
QCA	Quality compliance audit
QCI	Quality control initiative
QCMD	Quality Control for Molecular Diagnostics
QF-PCR	Quantitative fluorescent polymerase chain reaction
QIT	Quality Improvement Tool
QMS	Quality management system
RA	Rheumatoid arthritis
RACL	Relational algebraic capacitated location
RCCH	Red Cross War Memorial Children's Hospital
RCE	Regional Centre of Excellence
R&D	Research and Development
RDC	Research Development Committee
RDT	Rapid Diagnostic Test
RDTMP	Research development training and mentorship programme
REDCap	Research Data Capture
RfA	Results for Action
RFH	Rheumatoid Factor
RFLP	Restriction fragment length polymorphism
RFQ	Request for Quotation
RHRC	Remuneration and Human Resources Committee

ABBREVIATIONS AND ACRONYMS (CONTINUED)

RIA	Radioimmunoassay
RIC	Research and Innovation Committee
RIF	Rifampicin
RPR	Rapid plasma reagin
RSV	Respiratory syncytial virus
RT–PCR	Real-time polymerase chain reaction
RTQII	Rapid test quality improvement initiative
RVFV	Rift Valley fever Virus
RXH	Red Cross Academic
SAAVI	South African AIDS Vaccine Initiative
SABMR	South African Bone Marrow Registry
SACCESS	South African Collaborative COVID-19 Environmental Surveillance
SACMC	South African COVID-19 Modelling Consortium
SACOMD	South African Committee of Deans of Medical Schools
SADC	Southern African Development Community
SAHCS	Southern African HIV Clinicians Society
SAHPRA	South African Health Products Regulatory Authorities
SAIOH	Southern African Institute for Occupational Hygiene
SAIMR	South African Institute for Medical Research
SALDA	South African Laboratory Diagnosis Association
SAMA	South African Medical Association
SAMRC	South African Medical Research Council
SANAS	South African National Accreditation System
SANBS	South African National Blood Services
SANDF	South African National Defence Force
SANReN	South African National Research Network
SAPHRA	South African Health Products Regulatory Authorities
SAPPHGenE	South African-Pittsburgh Public Health Genomic Epidemiology Research Training Programme
SAPS	South African Police Service
SARS-CoV-2	Secure Acute Respiratory Syndrome Coronavirus 2
SARI	Severe acute respiratory infection
SASOHN	South African Society of Occupational Health Nursing Practitioners
SASOM	South African Society of Occupational Medicine
SAVP	South African Vaccine Producers
SAVQA	South African viral quality assessment
SBE	Snakebite envenoming
SCC	Staphylococcal cassette chromosome
SDG	Sustainable development goal
SDL	Skills Development Levy
SDW	Statistical Data Warehouse
SFLC	Serum free light chains
SHE	Safety, health and environment
SKR	Scientific Knowledge Centre
SLA	Service level agreement
SLE	Systemic lupus erythematosus
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SME	Subacute measles encephalitis
SMS	Short Message Service

ABBREVIATIONS AND ACRONYMS (CONTINUED)

SNP	Single nucleotide polymorphism
SOE	State-owned enterprise
SOP	Standard operating procedure
SPF	Specific-pathogen-free
SPI-RT	Stepwise Process for Improving the Quality of HIV Rapid Testing
STEA	Scientific travel and events attendance
STI	Sexually transmitted infection
TAT	Turnaround time
TB	Tuberculosis
TBH	Tygerberg Hospital
TDM	Therapeutic Drug Monitoring
TDH	Tshwane District Hospital
TENET	Tertiary Education and Research Network of South Africa
TEPHINET	Training Programs in Epidemiology and Public Health Interventions Network
TMS	Tissue microarray analysis
ToR	Terms of reference
ToT	Training of trainers
TQM	Total Quality Management
T-RFLP	Terminal restriction fragment length polymorphism
TTAC	Technologist and Technician Advisory Committee
TTO	Technology Transfer Office
TWAS	The World Academy of Sciences
TWG	Technical Working Group
UCT	University of Cape Town
UI	user interface
UIF	Unemployment Insurance Fund
U&E	Urea and electrolytes
UFS	University of the Free State
UKZN	University of KwaZulu-Natal
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UoT	University of Technology
SU	Stellenbosch University
USAID	United States Agency for International Development
UTT	Universal Test and Treat
VDPV1	Vaccine-derived poliovirus type 1
VDPV2	Vaccine-derived poliovirus type 2
VOIP	Voice over Internet Protocol
VL	Viral Load
VPN	Virtual Private Network
WCA	Workers Compensation Assistance
WCL	Western Cape Laboratories
WDGMC	Wits Donald Gordon Medical centre
WGS	Whole-genome Sequencing
WHO	World Health Organization
WHO/AFRO	WHO Regional Office for Africa
WIL	Work-integrated learning
Wits	University of the Witwatersrand
WSP	Workplace skills plan
XDR	Extensive drug resistance

FOREWORD BY THE CHAIRPERSON

INTRODUCTION

It is my pleasure to be able to report that the NHLS has performed well, making every effort to deliver on its mandate as well as rising to meet the challenges brought on by the COVID-19 pandemic, while playing its role as per its mandate and implementing a COVID-19 testing strategy.

Sadly, we have lost employees to COVID-19. These are colleagues who sacrificed their lives to serve others. We are deeply saddened by this, not only by the loss of lives, but also the loss of exceptional individuals. We thank their families for allowing their loved ones to serve our country. We remember and salute all of them.

This annual report is feedback to our stakeholders on the work done by the NHLS during the 2021/22 financial year in pursuing its mandate. It is an appraisal of the extent to which the organisation has managed to implement the strategy, as well as the 2021/22 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 2021/22 financial year. During the review period, work was done against a backdrop of increased expectations in 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 subsidiaries include the National Institute for Communicable Diseases (NICD), the National Institute for Occupational Health (NIOH), and the South African Vaccine Producers (SAVP). The NHLS has laboratories in all nine provinces, employing approximately 8 387 people. Diagnostic laboratory service, research, teaching and training, and the development of anti-snake and other venom sera, as well as reagents and media, are among its activities.

Our primary responsibility as the Board is to provide 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 (CEO), Dr Kamy Chetty, several impactful decisions were 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 diseases;
- monitoring of tuberculosis (TB) diagnosis and treatment;
- the screening for cervical cancer; and
- the support of occupational health services.

STRATEGIC OVERVIEW

Our strategic plan allowed us to make an overall assessment of our achievements and shortcomings, and to determine our future in light of the challenges that lie ahead. It highlights four key strategic goals to position the NHLS as a progressive diagnostic pathology service aspiring to quality, equitable and accessible healthcare. The prioritised strategic outcomes are outlined as follows:

- clinical-effectiveness and efficiency;
- high-quality services;
- cost-effective services; and
- providing good governance.

LABORATORY SERVICE

Laboratory testing is a pillar of the COVID-19 outbreak response. The NHLS continued to offer timeous and high-quality service to the public as evidenced by the achievement of the required turnaround time of almost all the targets as set in the APP. The NHLS has reacted early and collectively to the COVID-19 pandemic, ramping up diagnostic capacity to meet the challenges posed by the pandemic. While COVID-19 testing was urgent, the NHLS continued to conduct routine or traditional tests for human immunodeficiency virus (HIV), tuberculosis (TB), and cervical cancer for the public health system through its nationwide network of laboratories.

ACADEMIC AFFAIRS, RESEARCH, AND QUALITY ASSURANCE

The Academic Affairs, Research and Quality Assurance department 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). On the quality assurance front, the NHLS continued to implement and improve the Quality Management System (QMS) in laboratories and departments against different international standards. SANAS was able to conduct an initial assessment in multiple laboratories during the reporting period, increasing the number of accredited diagnostic laboratories.

SURVEILLANCE OF COMMUNICABLE DISEASES

The NICD continued to play a pivotal role in ensuring prompt interventions regarding communicable disease outbreaks such as COVID-19 in South Africa. To highlight some of the achievements, the Division of Public Health Surveillance and Response (DPHSR) played a pivotal role in the national COVID-19 pandemic response through the Emergency Operations Centre (EOC), the Outbreak Response Unit (ORU), and the Provincial Epidemiology Team. This included daily epidemiological updates to the National Department of Health (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 comorbidities on COVID-19 mortality.

OCCUPATIONAL HEALTH AND SAFETY

The COVID-19 pandemic is one of the biggest challenges that societies and businesses have faced. The NIOH is one of the divisions of the NHLS that plays a significant role in the provision of occupational health and safety services to workplaces, both in the formal and informal sectors of the economy. As we have witnessed, the pandemic impacted workplaces across the globe, and the NHLS certainly was no different. The NIOH provided substantial advice and guidance to the NHLS Board and executive management in drafting mitigating strategies and updating health and safety policies. The institute took the lead in creating awareness and advising workplaces – both in the public and private sectors – on assuaging and preventing the spread of the pandemic.

ADMINISTRATION

The role of administration is vital to the NHLS, where service delivery is driven by effective and efficient administration through a range of support services. These services range from human resources, labour relations, and information technology to property management, security, legal services, communication, and integrated planning. However, four key programmes are in place to keep these vital elements of the organisation on track, namely, financial management, governance and compliance, information and technology, and human resources management.

THE NHLS BOARD

During the financial year under review, the Board appointed Ms Makgopelo Mkhwanazi as Executive Manager for Human Resources on 01 June 2021. We look forward to supporting her as she continues to drive the Human Resources stability of the organisation under the leadership of the CEO, Dr Chetty. Equally, we are pleased to announce the appointments of Dr Spo Kgalamono as Executive Director of the NIOH and Prof Adrian Puren as Executive Director of the NICD. Both Dr Kgalamono and Prof Puren bring a wealth of experience in their respective fields, and have proven their abilities. The Board wishes them every success as they continue to lead the two institutes.

ACKNOWLEDGEMENTS

What is also noteworthy is that, over this period, the NHLS maintained an unqualified audit opinion with findings from the auditors, which speaks to the quality of the leadership of the institution. As the NHLS, we are proud of these achievements. We will endeavour to build on them to leave a lasting legacy for future generations, both at an institutional and societal level. I would like to express my sincere gratitude to the Minister of Health and the Deputy Minister for their support to the NHLS. I am also thankful to the Director-General of Health for his support and wisdom. I also 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.

On behalf of the Board, I would like to express my appreciation to the NHLS executive management team, led by the CEO, Dr Kamy Chetty, who has superbly steered this organisation to the marvel it has become.

As we move forward in the 2022 year and beyond, I am proud of these achievements. May you continue to make this transformed organisation admirable. On behalf of the NHLS Board and the NHLS executive management team, I commit to ensuring that South African citizens receive high-quality diagnostic service timeously.

To the NHLS executive management team and staff, I am humbled by the trust and respect you have shown us as we both continue to build a mutually beneficial working relationship at the Board level.

Prof Eric Buch
Chairperson

Date: 22 August 2022

CHIEF EXECUTIVE OFFICER'S OVERVIEW

INTRODUCTION

I am humbled to once again join the Board in presenting the NHLS Annual Report for the 2021/22 financial year. Despite the havoc caused by COVID-19 and the resultant challenges that characterised the year under review, the NHLS still managed to deliver on its mandate and ensured that service delivery continued seamlessly.

For the fourth year in succession, the NHLS has maintained an unqualified audit opinion with findings. The NHLS also achieved 88% of its set targets against the approved APP targets compared to 86% in the previous financial year. This outstanding performance is announced with the greatest sense of pride, given the challenges endured.

I am also pleased to report that the NHLS hosted a successful virtual Pathology Research and Development (PathReD) Congress in August 2021, first of its kind in the NHLS. The PathRed Congress is a biennial meeting that was inaugurated in 2015 to share scientific knowledge, build expertise, strengthen capacity, and hone the skills of emerging professionals in pathology and public health disciplines.

FINANCIAL OVERVIEW

Our cash balance has increased to R3.5 billion. The NHLS has successfully demonstrated its ability to pay its current liabilities out of current assets and has exceeded the standard ratio of 2:1.

Our creditor days have increased to 36 days, which is a marginal increase from the prior year. The NHLS experienced a 16% increase in total volumes compared to the prior financial period. The NHLS revenue grew by 16% compared to the prior year and this is due to test revenue generated from COVID-19 testing. The NHLS collected R11.6 billion from provincial departments compared to R9.7 billion in the prior year.

As of 31 March 2022, the trade recievables amounted to R6.6 billion. Most 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 timely payments of debt in arrears.

The NHLS total assets increased from a restated R7.4 billion, in the prior year, to R7.8 billion, in the current year.

PEOPLE MANAGEMENT

In line with our mandate as a research and development institution, we continued to implement sound human resource interventions that have an internal and external focus. Development interventions that have an internal focus are implemented in recognition of NHLS core staff and other support staff as the single-most-important resource that enabled us to record the achievements that we outline in the rest of this report. It is for this reason that our human resources programme continues to see an uptake of staff bursaries that exceeds expectations. A total of 221 employees were awarded staff bursaries as part of their personal growth and development. The NHLS, together with labour, will continue to maintain a healthy working relationship.

IMPROVEMENTS IN SYSTEMS

The NHLS Information Technology and Communication department has pieced together unique solutions to enhance efficiency in NHLS business operations through continual efforts to improve systems.

As such, several IT-related projects were implemented in the year under review. This includes 233 NHLS sites, which were successfully migrated over to MTN from DV8 by the end of July.

As part of the LAN Refresh Project, IT department has installed 248 switches at 49 sites, including data centres. Access points for WIFI installed were 107 out of 150 sites. This improved the security and throughput speeds within the local area network. The bandwidth has improved on a number of sites.

Server and data storage infrastructure equipment have been upgraded in both data centres. The new infrastructure hosts our Microsoft, ECM and other key systems except for CDW and Oracle. The old equipment being replaced is now being utilised for development and testing platforms. Installation and migration of environments have been completed. Microsoft Office 365 was successfully rolled out to 500 staff members.

QR codes on COVID-19 reports have been successfully implemented. This has become mandatory for airlines for international flights out of the country. This allows for the verification of information by scanning QR codes for authenticity.

TrakCare slow responses have improved while the NHLS, together with InterSystems, is examining the design and architecture of the system to see where further improvements can be made. CDW reports to the provinces have been delivered successfully with minimal delays.

On governance and reporting, information security and governance policies have been reviewed, and new policies have been developed. In addition, the vulnerability scan of the Oracle environment has been completed.

The NHLS will continue to invest in the IT infrastructure and strengthen it.

SERVICE DELIVERY

The total test volumes increased by 16% (from 92 471 586 in 2020/2021 to 106 837 537 in 2021/2022). The test volumes could be attributed to the easing of COVID-19 restrictions, enabling patients to go to the health facilities as well as the number of COVID-19 tests performed.

The national priority tests generally increased in 2021/2022 financial year when compared to the same period in the previous financial year. Although COVID-19 impacted negatively on the TB programme in the previous year, it recovered in the 2021/2022 financial with an increase of 39% in test volumes when compared to the same period in the previous financial year.

In response to COVID-19, an additional 110 GeneXpert (GX4) instruments were procured with 10-colour functionality. This has facilitated the planning for implementation of the Xpert MTB/XDR assay, resulting in the ability to perform reflex testing for drug resistance using one sputum specimen instead of two. This functionality came as a game-changer in the rapid diagnosis of drug-resistant TB.

The TB World Day was held on 24 March 2022 in Kimberley. The commemorations of this day were led by the Deputy President David Mabuza and the NHLS was one of the participating organisations. The NHLS in partnership with the NDoH conducted roadshows using the NHLS mobile laboratories, visiting communities particularly the most isolated, and conducting TB screening and on site testing.

THE YEAR AHEAD

The coronavirus pandemic has had a devastating impact on the socio-economic aspects of our country . Within the NHLS, we have lost a number of valued and loved staff. We feel the impact of these losses and our thoughts are with the families. The impact on the economy will have a resultant impact on the NHLS. Therefore, we cannot afford to be complacent going forward. We will ensure that the NHLS is well prepared to deal with the future demand.

ACKNOWLEDGEMENTS

We will continue to put our shoulders to the wheel and work hand-in-hand with our stakeholders: the NHLS Board, the NDoH, provincial Departments of Health, and many other key role players in the health sector. We will ensure that the citizens of this country receive the best possible high-quality service from the NHLS. Most importantly, we will do everything possible to ensure that the NHLS is strategically positioned to implement National Health Insurance.

I am thankful for the support that the NHLS Board, the NDoH and the provincial Departments of Health provide to the NHLS. To the NHLS executive management team, your support and commitment have been nothing but exceptional. To the NHLS staff, without your dedication and hard work, the achievements recorded would not have been possible.

Dr Kamy Chetty
Chief Executive Officer

Date: 22 August 2022

BOARD MEMBERS

Prof Eric Buch
Chairperson

Prof Jeffrey Mphahlele
Vice-Chairperson

Dr Kamy Chetty
Chief Executive Officer

Prof Thanyani Mariba

Mr Koena Nkoko

Mr Michael Sachs

Dr Balekile Mzangwa

Prof Mpho Klass Kgomo

Dr Siseko Martin

Mrs Nicolene Van Westhuizen

Mrs Penelope Msimango

Dr Lesley Bamford

Mr Nick Buick

Dr Naledzani Ramalivhana

Mr Jonathan Mallett

Prof Tivani Phosa Mashamba-Thompson

Dr Mahlane Phalane

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

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

- All the 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 error-free;
- The annual report was prepared in accordance with the Annual Report Guidelines as issued by the 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 the judgements made on 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; and
- 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 **31 March 2022**.

Yours faithfully

Prof Eric Buch
Chairperson of the Board

Date: 22 August 2022

Dr Kamy Chetty
Chief Executive Officer

Date: 22 August 2022

OVERVIEW OF THE NATIONAL HEALTH LABORATORY SERVICE

The NHLS is a national public entity established in terms of the National Health Laboratory Service Act, No. 37 of 2000, governed by a Board to provide quality, affordable, and sustainable health laboratory services, training, and research. It was established in 2001 by amalgamating the former South African Institute for Medical Research (SAIMR), the National Institute for Virology and the National Centre for Occupational Health. It is managed according to the provisions of the National Health Laboratory Service Act, the NHLS Rules, and the Public Finance Management Act (PFMA), No. 1 of 1999 (as amended).

Through its countrywide network of quality-assured diagnostic laboratories, the NHLS is the sole provider of diagnostic pathology services to more than 80% of the South African population. It also provides surveillance support for communicable diseases, occupational health, and cancer.

It has a clear organisational structure consisting of a head office in Sandringham, Johannesburg, six regions (Eastern Cape; Free State and North West; Gauteng; KwaZulu-Natal; Limpopo and Mpumalanga; and Northern and Western Cape); and institutes, namely: The National Institute for Communicable Diseases (NICD), incorporating the National Cancer Registry (NCR) and the National Institute for Occupational Health (NIOH); Diagnostic Media Products (DMP); and South African Vaccine Producers (SAVP), a subsidiary.

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

There are currently three Diagnostic Media Products (DMP) Units within the NHLS, which are responsible for producing microbiological culture media and reagents for use in clinical diagnostic laboratories. The diagnostic media products are supplied internally to NHLS laboratories, as well as externally to private laboratories and some laboratories within Africa. The NHLS aims to consolidate these departments under single management and strengthen it to become one of the revenue-generating units.

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

THE NATIONAL HEALTH LABORATORY SERVICE

Vision

To provide a 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 well-being 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 for 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.

LEGISLATIVE AND OTHER MANDATES

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

CONSTITUTIONAL MANDATE

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

1. The Republic of South Africa's 1996 Constitution requires the state to gradually realise socioeconomic rights, including access to healthcare;
2. Section 27 of the Constitution stipulates the following regarding healthcare, food, water, and social security:
    (a) Everyone has the right to have access to the following:
        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; and
4. No one may be refused emergency medical treatment.

THE NATIONAL HEALTH ACT, NO. 61 OF 2003

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

The objectives of the NHA are to:

- Unite the various elements of the national health system in pursuit of a common goal to actively promote and improve South Africa's national health system;
- 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 that 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; and
- Create a foundation for the healthcare system that must be interpreted and implemented alongside other laws and policies that relate to health.

THE NATIONAL HEALTH LABORATORY SERVICE 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.

PUBLIC FINANCE MANAGEMENT ACT, NO. 1 OF 1999 (AS AMENDED)

The Act mandates to regulate financial management in the national government; to ensure that all revenue, expenditure, assets and liabilities of that government are managed efficiently and effectively; to provide for the responsibilities of persons entrusted with financial management in that government; and to provide for matters connected therewith.

The object of this Act is to secure transparency, accountability. and sound management of the revenue, expenditure, assets and liabilities of the institutions to which this Act applies.

ADDITIONAL GOVERNANCE CONTEXTS

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

- Preferential Procurement Framework Act, No. 5 of 2000
- Companies Act, No. 71 of 2008
- General rules established in terms of section 27 of the NHS Act
- Protocol on Good Governance in the Public sector
- King IV Code of Corporate Governance
- Treasury Regulations issued in terms of PFMA
- All laws that apply to the health sector

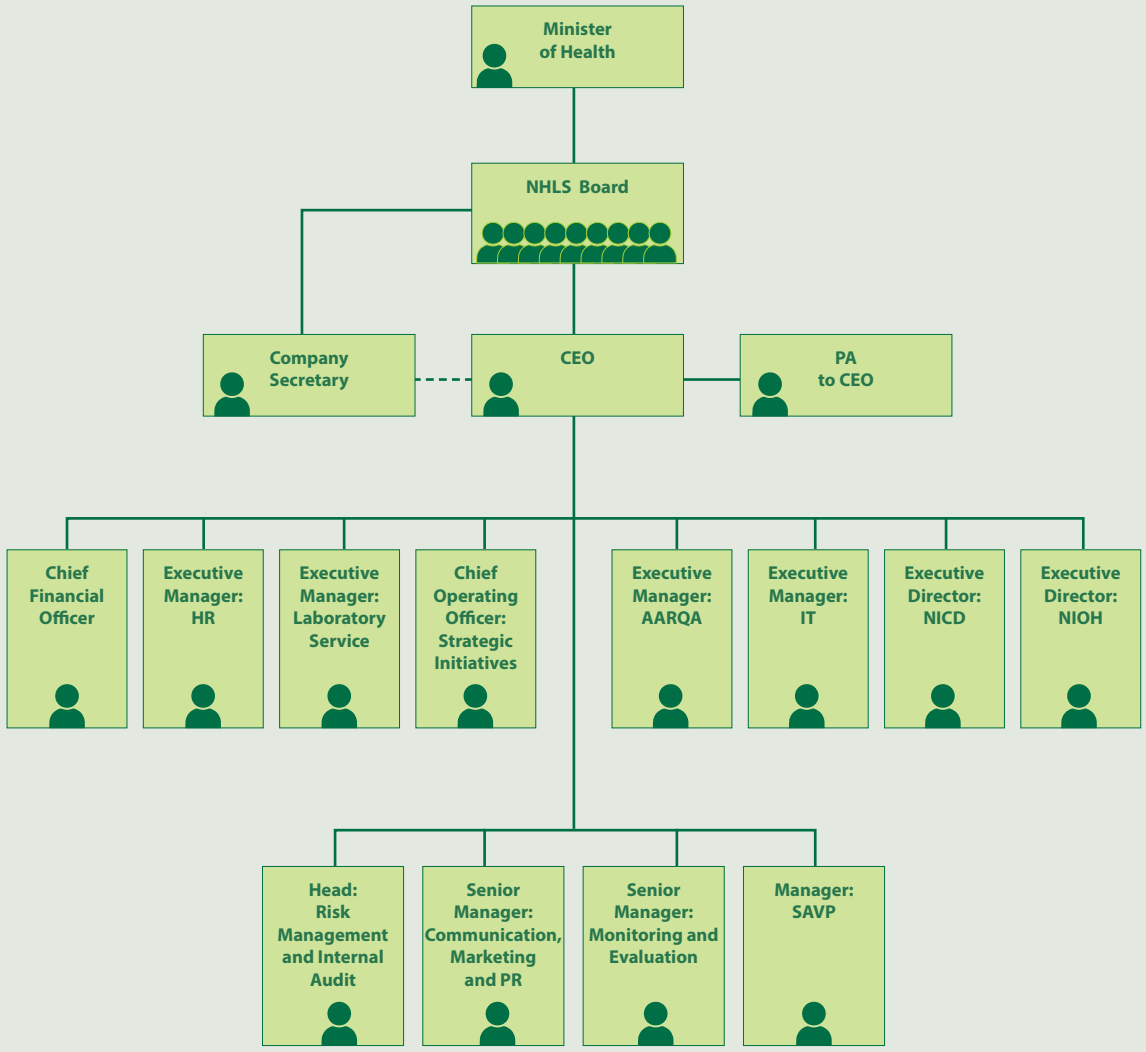
POLICY INITIATIVES

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

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

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

HIGH-LEVEL ORGANISATIONAL STRUCTURE



PART B

PERFORMANCE INFORMATION

AUDITOR'S REPORT PREDETERMINED OBJECTIVES

The independent auditor performed the necessary audit procedures 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 audit report with findings being reported under the 'predetermined objectives' heading in the report on section of the auditor's report on pages 162-168.

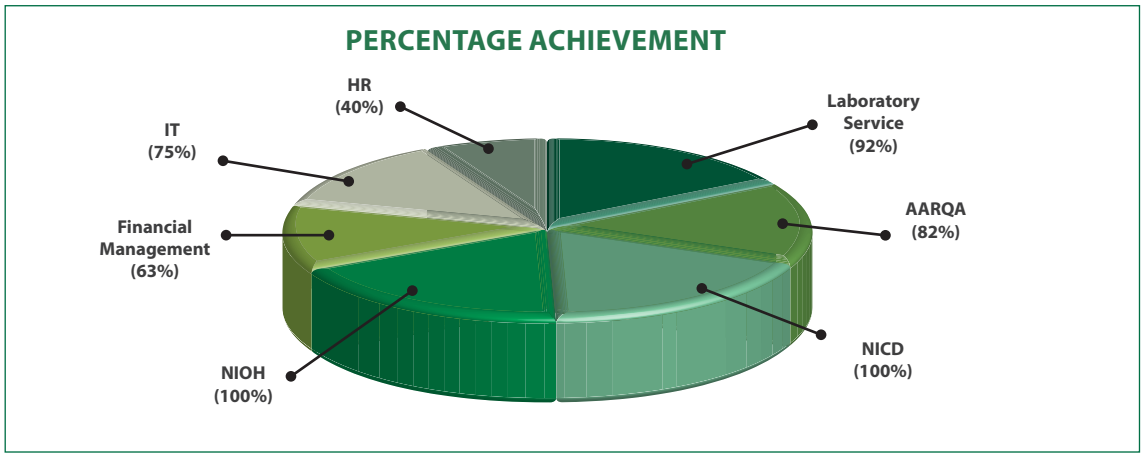
OVERVIEW OF PERFORMANCE

SERVICE DELIVERY ENVIRONMENT

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

The NHLS managed to achieve 88% of its set targets. The performance has significantly increased compared to the 86% reported in the previous financial year.

SUMMARY BREAKDOWN OF PERFORMANCE PER PROGRAMME



The NHLS continued to offer timeous and high-quality service to the public. This is evidenced by the achievement of the turnaround time of almost all the targets as set in the APP. In addition, the implementation of the Total Quality Management System resulted in the increase in the number of SANAS accredited laboratories and continues to improve the provision of high quality service in both the accredited and non-accredited laboratories.

ORGANISATIONAL ENVIRONMENT

Challenges in power supply and water scarcity have had a noticeable impact on the NHLS service delivery. As a result, some of the laboratories were unable to meet the set turnaround targets. To mitigate the above-mentioned challenges, the NHLS is working on increasing generator capacity in all the laboratories, and not relying entirely on the hospital generators, which are not always reliable. In addition, the NHLS experienced some challenges with internet connectivity, mostly due to interruptions in power supply.

In addition to the above-mentioned challenges, the NHLS was also negatively impacted by the looting incidents that occurred in KwaZulu-Natal and Gauteng. The incident negatively affected NHLS operations in both provinces. Despite this, the NHLS was able to timeously implement contingency actions to avoid testing delays and to ensure operations resumed as soon as possible.

Furthermore, the period under review was once again dominated by the COVID-19 pandemic, which continued to impact workplaces across South Africa. The Occupational Health and Safety Information System (OHASIS) was adapted to cater to COVID-19 test results and provide weekly statistics to the NHLS EXCO and COVID-19 Compliance Officers. The updates included a specific COVID-19 disease report for the online screening of employee symptoms, which supported and provided summaries for the dedicated COVID-19 dashboards. Each self-report allows perusal by an occupational health (OH) nurse or a SHE Officer. In addition, both self-reported vaccinations and those captured by an OH nurse were recorded.

The cumulative positive COVID-19 cases as reported into OHASIS from the start of the pandemic in 2020 until 20 April 2022 was 4 596. The response to and management of employees suspected to have COVID-19 and confirmed positive cases continued through the Safety, Health and Environment (SHE) Department. Screening for symptomatic workers with appropriate referrals for COVID-19 testing remains active.

INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

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 or outside of South Africa that may require such services; and any private health care provider that requests such services. It is anticipated that the NHLS will provide equitable, comprehensive, quality, timely and cost-effective pathology services, resulting in improved patient care.

Table 1: Programme 1: Laboratory Service

Outcome	Output	Output indicators	Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Clinical effectiveness and efficiency	Modernised laboratory services	Develop and implement a service delivery model	New	Service delivery model developed	Service delivery model developed	Service delivery model developed	0	This was achieved towards the end of the financial year in 2020/2021 and could not be removed from the 2021/2022 APP because the APP was approved and signed by the Minister at that time.
		Develop and implement the specimen tracking system	New	Achieved	Specimen tracking system developed	Specimen tracking system developed	0	This was achieved towards the end of the financial year in 2020/2021 and could not be removed from the 2021/2022 APP because the APP was approved and signed by the Minister at that time.
	Improved turnaround times	Percentage of TB Microscopy tests performed within 40 hours	95%	96%	92%	94%	2%	TB test volumes decreased during the year and started picking up toward the end of the year. The drop in test volumes resulted in a slight improvement in the turnaround times. In addition, the increase in the number of SANAS accredited laboratories, especially district laboratories, led to improved efficiencies, which led to improved turnaround times.
		Percentage of TB GeneXpert tests performed within 40 hours	90%	95%	92%	94%	2%	
		Percentage of CD4 tests performed within 40 hours	90%	95%	93%	93%	0	N/A

Outcome	Output	Output indicators	Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Clinical effectiveness and efficiency (continued)	Improved turnaround times (continued)	Percentage of HIV Viral Load tests performed within 96 hours	75%	80%	80%	93%	13%	The turnaround time was previously impacted by the installation of new instruments and the preparation of the laboratories to start with the implementation of the new instruments. The turnaround time started improving as the process gradually came to completion, also reinforced with the correction of instrument teething challenges. The tender implementation was completed in 2021, hence the programme has been stable for most of the 2021/2022 financial year.
		Percentage of HIV PCR tests performed within 96 hours	85%	83%	80%	90%	10%	
		Percentage of cervical smear screening performed within five weeks	90%	95%	90%	97%	7%	Test volumes started increasing post-COVID-19 pandemic and overtime had to be implemented for both pre-analytic and analytical phases to improve the turnaround time.
		Percentage of laboratory tests (FBC) performed within eight (8) hours	90%	96%	93%	95%	2%	Although the test volumes increased when compared to the same period in the previous year, the impact of the increase in the number of SANAS accredited laboratories, especially the district laboratories, resulted in improved efficiencies in the laboratories, which resulted in improved turnaround times.
		Percentage of laboratory tests (U&E) performed within eight (8) hours	94%	94%	93%	91%	-2%	Loadshedding and water shortage have impacted negatively in some of the laboratories, especially in the Eastern Cape. The NHLS is working on increasing generator capacity in all the laboratories and not be totally reliant on the hospital generators, which are not completely reliable.

Outcome	Output	Output indicators	Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Clinical effectiveness and efficiency (continued)	Equitable service coverage	Develop and implement a Point-of-Care-Testing (POCT) plan	New	Point-of-care-testing plan developed	Point-of-care-testing plan developed	A point-of-care-testing plan has been developed.	0	The 2020–2021 focused more on the development of the pilot implementation plan, and this was expanded in 2021/22.
		Implement digital pathology	New	Not achieved	Develop an implementation plan	The implementation plan has been developed.	0	N/A

Linking performance to budget: Programme 1: Laboratory Service

	Audited	Audited	Budget	Actual expenditure	(Over)/Under expenditure	Reason/s for (over)/under expenditure
R000's	2019/2020	2020/2021	2021/2022	2021/2022	2021/2022	2021/2022
Total expenses	6 830 737	7 179 525	8 532 391	909 463	-477 072	The overspend is due to the higher volume of tests performed compared to what was budgeted. The cost of the additional tests has resulted in an overspend against the budget.

Programme 2: Academic Affairs, Research and Quality Assurance

Programme purpose

The main purpose of this programme is to strengthen the mandate of the NHLS of maintaining and providing quality-assured and accredited laboratory medicine on the academic platform. Two 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 high-quality technical skills in pathology for the NHLS and the rest of the country. This mandate strengthens the business case for the 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 while promoting the exploration of innovative emerging technologies that will enhance the capacity of South African research and development for novel ideas.

Table 2: Programme 2: Academic Affairs, Research and Quality Assurance

Outcome	Output	Output indicators	Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
High-quality services	Strengthened total quality management systems	Percentage compliance achieved by laboratories during annual quality compliance audits	90%	100%	92%	98%	6%	The implemented Quality Management System continues to improve in non-accredited laboratories. This is due to the competency of staff; the quality of equipment used; continuous monitoring and training; and the implementation of improvement plans in the laboratories.
		Percentage of laboratories achieving proficiency testing scheme performance standards of 80%	90%	99%	90%	99%	9%	The implemented Quality Management System continues to improve in non-accredited laboratories. this is due to the competency of staff; the quality of equipment used; continuous monitoring and training; and the implementation of improvement plans in the laboratories.
		Number of National Central laboratories that are SANAS-accredited	53	51	52	52	0	N/A
		Number of Provincial Tertiary laboratories that are SANAS-accredited	13	13	15	15	0	N/A

Outcome	Output	Output indicators	Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
High-quality services (continued)	Strengthened total quality management systems (continued)	Number of Regional laboratories that are SANAS-accredited	12	29	28	30	2	N/A
		Number of District laboratories that are SANAS-accredited	10	35	28	42	14	Most of the laboratories were assessed and recommended for accreditation in 2020-2021. Accreditation was completed in 2021-2022, hence the overachievement.
		Number of ISO 9001 certified departments	3 departments	3 departments	4 departments	4 departments	0	N/A
		Develop and implement the pathologists' national coverage plan	New	The pathologists' national coverage plan approved	20% implementation of the pathologists' national coverage plan	30% implementation of the pathologists' national coverage plan	10%	The strategies that were implemented enabled the overachievement. The following was done to increase coverage: 1)Telephone availability of the pathologists to all the laboratories; 2)Clinical rotation of pathologists to laboratories that do not have resident pathologists; and 3)Training support through the ECHO support (virtual training system).
	Cutting-edge health research	Number of articles published in the peer-reviewed journals	600	673	640	688	48	The increased output of research was driven by increased research on COVID-19.

Outcome	Output	Output indicators	Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Clinical effectiveness and efficiency	Appropriately trained human resources in adequate numbers	Number of pathology registrars admitted and trained in the NHLS	30	46	30	64	34	The NHLS is the only institution that trains pathologists in South Africa. The number of registrars trained depends on the number of the registrars available on the platform
		Number of intern medical scientists admitted and trained in the NHLS	50	55	50	31	-19	Recruitment was initiated and completed in the middle of March 2022. The appointment of the intern medical scientists is effective from the 1st of April 2022. Unfortunately, the 21 newly appointed intern medical scientists cannot be included in the 2021-2022 financial year calculation.

Linking performance to budget: Programme 2: Academic Affairs, Research and Quality Assurance

	Audited	Audited	Budget	Actual expenditure	(Over)/Under expenditure	Reason/s for (over)/under expenditure
R000's	2019/2020	2020/2021	2021/2022	2021/2022	2021/2022	2021/2022
Total expenses	88 800	185 742	617 69	383 315	-321 545	Academic Affairs includes all NHLS grant funding expenses. This grant funded expenditure is not budgeted for, hence the variance between budgeted expenses versus actual expenses. It must be noted that all grant-funded expenses are recovered from the grantor.

Programme 3: Surveillance of Communicable Diseases

Programme purpose

The NICD is a national public health institute for South Africa that provides reference microbiology, virology, epidemiology, surveillance, and public health research to support the government's response to communicable disease threats.

Table 3: Programme 3: Surveillance of Communicable Diseases

Outcome	Output	Output indicator	Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
High-quality services	A robust and efficient communicable disease surveillance system and outbreak response	Percentage of identified prioritised diseases under surveillance	90%	90%	90%	98%	8%	There is a better tracking systems in place, and because of this, the Surveillance Officers were able to fill in the case report forms on time. We also have a better tracking system now.
		Percentage of outbreaks responded to within 24 hours after notification	100%	100%	100%	100%	0	N/A
		Percentage of 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	The report can be found on https://www.nicd.ac.za/centres/national-cancer-registry/
High-quality services	A robust and efficient communicable disease surveillance system and outbreak response	Number of NICD laboratories with WHO reference status	7 laboratories with WHO reference status.	7 laboratories	7 laboratories with WHO reference status.	7 laboratories with WHO reference status	0	N/A
		Number of articles published in the peer-reviewed journals	130	200	130	257	127	The increased output of research was driven by increased research on COVID-19.
		Number of field epidemiologists qualified	7	7	7	8	1	N/A

Linking performance to budget: Programme 3: Surveillance of Communicable Diseases

	Audited	Audited	Budget	Actual expenditure	(Over)/Under expenditure	Reason/s for (over)/under expenditure
R000's	2019/2020	2020/2021	2021/2022	2021/2022	2021/2022	2021/2022
Total expenses	410 370	398 525	414 554	420 264	-5 710	The NICD has received a budget cut for three years consecutively. The NHLS is currently funding the shortfall

Programme 4: Occupational and Environmental Health and Safety

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

Programme purpose

The NIOH is a National Public Health Institute that 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 MBDO 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.

Table 4: Programme 4: Occupational and Environmental Health and Safety

Outcome	Output	Output indicator	Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
High-quality services	Robust and efficient occupational and environmental health services	Percentage of occupational and environmental health laboratory tests conducted within the predefined turn-around time	90%	97%	90%	98%	8%	The target was overachieved because test volumes decreased during the financial year
		Number of occupational, environmental health, and safety assessments completed	30	15	15	16	1	N/A
		Number of occupational health surveillance reports produced	4	4	4	4	0	N/A
		Percentage of NIOH laboratories that are SANAS-accredited	New	100%	100%	100%	0	N/A

Linking performance to budget: Programme 4: Occupational and Environmental Health and Safety

	Audited	Audited	Budget	Actual expenditure	(Over)/Under expenditure	Reason/s for (over)/under expenditure
R000's	2019/2020	2020/2021	2021/2022	2021/2022	2021/2022	2021/2022
Total expenses	137 078	135 843	156 224	141 252	14 972	The NIOH has received a budget cut for three years consecutively. The current under expenditure is due to the NIOH having to implement the necessary cost containment measures due to the reduction in funding.

Programme 5: Administration

Programme purpose

The administration programme plays a crucial role in the delivery of NHLS services by providing 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 processes 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:

Financial Management

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

Table 5: Sub-Programme: Financial Management

Outcome	Output	Output indicator	Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Cost-effective services	Improve liquidity position of the NHLS	Ratio of current assets to current liabilitiess	2:1	3,4:1	2:1	3,8:1	1,8:1	This has been above the target, due to the current assets higher than the liabilities, therefore NHLS has being able to pay its current liabilties.
		Cash flow coverage ratio (Operating cash in-flows/total debt)	1.5:1	4,2:1	2:1	3,5:1	1,5:1	This is due to the significantly high cash and cash equivalent payable from exchange
		Number of creditor days	30 days	23 days	30 days	28 days	-2 days	Achieved: The NHLS has achieved its creditors' days. More efforts have been made by the AP team to assist in requesting purchase orders and sending them to users for receipt, and users have responded positively. Hence, there is a great improvement in the number of creditors' days. SCM also made a huge contribution by resolving most of the price variance issues, which released most of the invoices on hold due to price variance.

Outcome	Output	Output indicator	Audited/actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Cost-effective services (continued)	Improve liquidity position of the NHLS (continued)	Number of debtors' days	250 days	109 days	115 days	129 days	14 days	Not all provinces were able to honour their financial commitments. Payments received from provinces were inadequate to cover their current and old debt. This has led to an increase in debtors' days.
		Percentage turnaround time for awarding tenders within 90 days.	80%	69%	90%	33%	-57%	The KPI was separated into the tenders that are below R10million and the ones that are above R10 million. The tenders that are above R10million has to go to the Board for approval. The bulk of the tenders are below R10million and separating the two will assist in improving the turnaround time for awarding the tenders.
	Reduced cost of pathology services to the clients	Develop and implement revenue and costing strategy.	New	Revenue and costing strategy developed	Implement 30% of the revenue and costing strategy	31% of the revenue and costing strategy has been implemented.	1%	N/A
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 tip-off platform that are investigated within 180 days	New	92%	90%	96%	6%	The reason for overachieving was the assistance of the panel of auditors to perform other investigations.

Information and Communication Technology (ICT)

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

Table 6: Sub-Programme: Information and Communication Technology

Outcome	Output	Output indicator	Audited/actual/planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Clinical effectiveness and efficiency	Modernised Information Technology systems	Develop and implement a real-time communication system with patients	New	Real-Time communication system with patients developed and included messages to patients for COVID-19 results	Send SMS to 20% of patients who provided cellphone numbers and gave consent	SMS was sent to 100% of patients who provided cellphone numbers and gave consent	80%	Implemented for COVID-19 testing. All (100%) of the patients who provided a valid cell number got their results via SMS.
		Implement the interface between NHLS LIS and the HPRS	New	Not Achieved	40% implementation of the HPRS	100% implementation	60%	An interface has been implemented. All the sites using HPRS can send HPRN to the NHLS and it will be used.
		Develop and implement the order entry system	New	Order entry system developed	Implementation of the order entry system in 20% of facilities that have internet connectivity.	Not achieved	-20%	Order entry system requirements have been rescoped. Development of the system is currently in progress.
		Percentage System Uptime for Critical Systems at laboratory level	99%	100%	99%	99%	0%	N/A

Human Resources Management

The purpose of the sub-programme is to provide effective services through efficient processes, systems and adequate human resources.

Table 7: Sub-Programme: Human Resources

Outcome	Output	Output indicators	Audited/Actual/ planned performance		Planned annual target	Actual achievement	Deviation from the planned target	Reason for deviation
			2019/20	2020/21	2021/22	2021/22		
Clinical effectiveness and efficiency	Appropriately trained human resources in adequate numbers.	Staff Turnover ratio	5%	3%	5%	4,6%	-0.4%	N/A
		Average staff recruitment turnaround time within 90 days	80%	96%	90%	94%	4%	The availability of managers to perform interviews physically or virtually has contributed to the improved recruitment turnaround time.
		BBBEE compliance	New	Not achieved	Level 5	Not achieved	Not achieved	The focus in the year under review was on improved internal processes. The NHLS has sourced expertise from the external service provider to assist with improving our BBBEE score.
		Number of intern medical technologists and student medical technicians admitted and trained in the NHLS	200	251	250	285	35	Intake of intern medical technologists depends on the demand from the universities of technology.
	Performance driven workforce	Percentage of employees with approved and evaluated performance agreements	95%	89%	98%	99%	Management implemented efficient monitoring and follow-up processes in place.	N/A

Linking performance to budget: Programme 5: Administration

	Audited	Audited	Budget	Actual expenditure	(Over)/Under expenditure	Reason/s for (over)/under expenditure
R000's	2019/2020	2020/2021	2021/2022	2021/2022	2021/2022	2021/2022
Total Expenses	1 167 514	3 880 030	1 160 049	2 613 564	-1 453 515	The administration programme carries the consolidated debt impairment for the entire NHLS. This has had a negative impact of R1,2bn for the period under review. This is a main driver for the overspend on the administration programme.

Reason - The administration programme carries the consolidated debt impairment for the entire NHLS. This has had a negative impact of R1,2bn for the period under review. This is a main driver for the overspend on the administration programme.

BUSINESS UNIT PERFORMANCE

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 UoTs; 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;
- National Priority Programmes (NPP);
- Academic Affairs, Research and Quality Assurance (AARQA);
- 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

LABORATORY SERVICE

AREA MANAGERS

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 Sustainable Development Goals reaffirm a global commitment to achieve universal health coverage by 2030. In the South African context, this means that all people and communities everywhere in the country should and must have access to the high-quality health services they need. Through its network of laboratories, which encompasses urban and rural locations in all nine provinces, the NHLS ensures equitable access to pathology services. It operates in six regions with the diagnostic offering appropriate to the level of care of a particular facility (a tiered service delivery model). This tiered model requires the integration of services with continuity of patient care as patients progress from primary health care facilities to other levels of care.

THE NHLS' NATIONAL FOOTPRINT

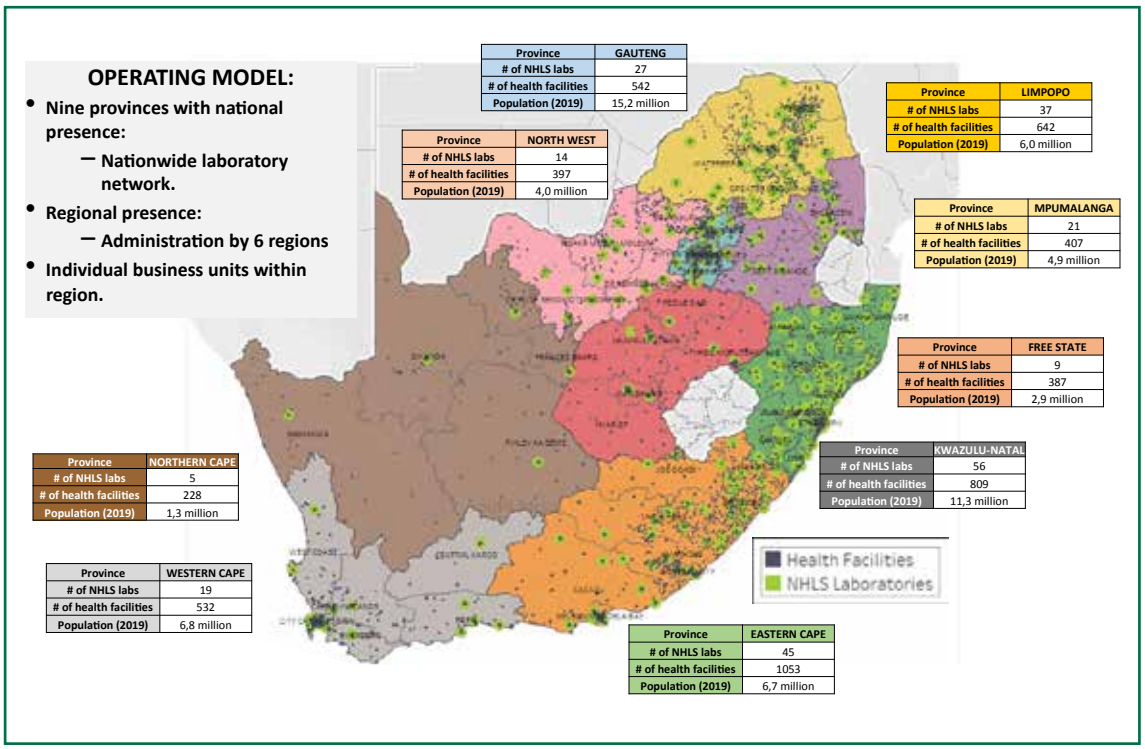


Photo 1: Laboratory Network and Operating Model

LABORATORY SERVICE - DIAGNOSTIC SERVICES AND NEW DEVELOPMENTS

Test volumes

A total of 106 837 537 tests were performed in 2021/22. This is an increase of approximately 16% compared to 2020/21. The eased COVID-19 regulations may have contributed to the increase in the number of tests performed because more people attended health institutions.

The national priority tests generally increased in the 2021/2022 financial year when compared to the same period in the previous financial year. Although COVID-19 had a negative impact on the TB programme in the previous year, the programme recovered in the 2021/2022 fiscal year, with a 39% rise in test volumes compared to the same period in the previous financial year.

Table 1. Total tests completed per province

Province	2020 to 2021	2021 to 2022
Eastern Cape	10 266 405	11 017 127
Free State	4 0432 224	5 455 296
Gauteng	29 006 091	29 174 909
KwaZulu-Natal	28 097 078	21 719 816
Limpopo	6 935 900	6 288 905
Mpumalanga	6 550 938	6 166 245
Northern Cape	2 151 681	2 100 139
North West	6 548 265	5 818 934
Western Cape	10 916 914	12 932 604

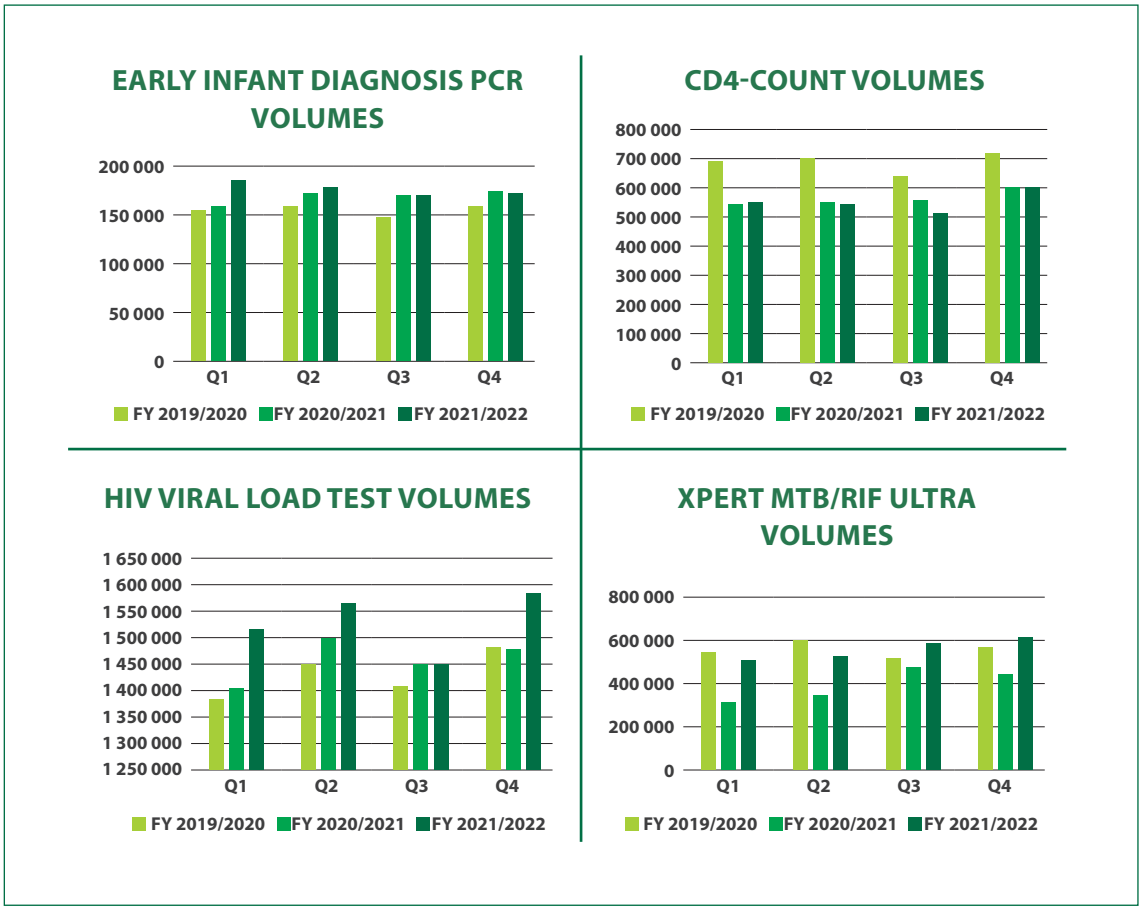


Figure 1. Year-to-year comparison of NPP tests (3-year comparison)

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 it is often used as a key performance indicator. In recent 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 2: Turnaround times of test results per region

Region	TB GXP	CD4	HIV VL	HIV PCR	Cervical smear	FBC	U&E
	Target =92%	Target =93%	Target =80%	Target =80%	Target =90%	Target =93%	Target =93%
Eastern Cape	93%	92%	92%	92%	98%	91%	89%
Free State	96%	97%	78%	68%	99%	94%	95%
Gauteng	97%	94%	93%	92%	94%	96%	85%
KwaZulu-Natal	93%	92%	95%	92%	97%	95%	93%
Limpopo	96%	92%	94%		99%	96%	95%
Mpumalanga	96%	92%	96%	90%	85%	94%	94%
Northern Cape	99%	98%				95%	94%
North West	95%	96%	94%	90%		93%	93%
Western Cape	97%	96%	91%	96%	99%	96%	98%

*** test referred outside the region*

Upgraded Laboratories

The NHLS' intention, among others, is to leverage innovation and new technology to improve efficiency and improve the laboratory infrastructure. To achieve this, the NHLS invested in upgrading the laboratories and improving the workflow and safety in the workplace.

Several regions completed major renovations in the year under review to improve workspace and accommodate new apparatus to improve efficiencies. The pictures below are evidence of some of the upgrades made in the year under review.

Newly revamped Botshabelo laboratory

Newly revamped Pelonomi laboratory

Newly revamped Welkom laboratory

Stakeholder Relations

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

Free State and North West

The Manager is part of the Blood Users Committee (BLUC) for hospitals. BLUC meetings are held monthly for DRH and quarterly for district hospitals, where issues such as TAT, EGK, MCDS, age analysis, consumables, and other issues are discussed. Relations with the University of the Free State remained excellent and amicably cooperative, as experienced at informal and formal meetings with the Dean at Institutional Academic Pathology Committee meetings.

Physical meetings were still very few due to the pandemic restrictions, and most people were still working from home. Where possible, engagements were done via digital platforms.

Eastern Cape

Collaboration between NHLS and Eastern Cape DoH was strengthened both at the district and provincial levels in the fight against the COVID-19 pandemic and participation in TB campaigns. The nursing staff has been very instrumental in responding to district requests to attend to COVID-19 outbreaks. The availability of mobile laboratories made it possible to meet the demand.

The laboratory manager of the Queenstown laboratory attended the World AIDS Day event on 01 December 2021, hosted by the provincial DoH in Chis Hani, Enoch Mgijima subdistrict.

Laboratory staff from Queenstown laboratory attending World AIDS Day

Gauteng

At the laboratory level and the provincial level, stakeholder interaction continues to strengthen relationships with the Gauteng DoH. The region is involved with stakeholders via Medical Advisory Committees, Laboratory User meetings, Pathology Management Committees, District meetings and clinic visits with representatives from the Gauteng DoH and their partners. It has an excellent relationship with stakeholders, including DoH partners. We strengthen these relations through several committees, meetings, and the Clinic Laboratory Interface Coordinator.

The South Rand laboratory made the region proud by winning an award for the tireless efforts they gave to the customers *-" Best Supporting Department".*

KwaZulu-Natal

Several meetings and engagements formed part of our continued stakeholder engagement, both physical and virtual. Client relations meetings and training sessions with the PHC and CHC clinics that drain to KEH were held, including COVID-19 training. Web view access for the clinics and hospitals was enabled for new doctors and clinic sisters to view the results. The training was conducted on rapid COVID-19 testing for 64 DoH employees. Customer satisfaction surveys for the laboratories were conducted, and the average score for the business units was 96.%.

Constant interaction with clients has strengthened the relationships with partners, DoH, SANDF, and Correctional Service Centres. This interaction happens at all levels, namely, the laboratory managers attending hospital management meetings, PHC meetings, and clinic visits; the Business Manager attending hospitals, district health meetings and district visits.

Limpopo

Relations with stakeholders were maintained through different types and levels of engagement throughout the year. However, these were limited due to ongoing restrictions related to the management of the COVID-19 pandemic. The NHLS supported and participated in the provincial commemorations of World AIDS Day and World TB Day, both held in the Vhembe district.

The NHLS roadshow for SANAS certificate handover by the regional Area Manager was attended by the provincial DoH and senior hospital management.

Various discussions with the provincial DoH on COVID-19 management, including border gate testing for COVID-19 antigen, were held at the service delivery level**.**

Mpumalanga

Stakeholder relations in Mpumalanga were continuously managed through engagements at different levels and programmes. Owing to COVID-19 pandemic restrictions, most of these engagements were held virtually.

The NHLS is an active member of the Laboratory and Blood Transfusion Committee set up by the Provincial DoH. At these meetings, NHLS makes inputs to improve the management of laboratory service costs and sample rejections in pathology services by the different hospitals.

There were also meetings with Port Health Management to resolve operational concerns and meet COVID-19 testing service delivery criteria at the border gates.

Meetings were held with the HIV and AIDS/STI/TB directorate (HAST) of the Mpumalanga DoH, where their 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 the stakeholders.

The NHLS participated in the World TB Day commemoration in the province, which was held in Daggakraal Clinic in GSN and Phola-Ntsikazi in Ehlanzeni District.

Western Cape

We maintained a strong working relationship with our stakeholders: The Western Cape Department of Health , UWC, UCT, CPUT, US, City of Cape Town Health, SANDF, DCS, environmental health and social welfare as well as private stakeholders.

Regular meetings are held to discuss and resolve issues as they occur.

The NHLS laboratories in the region continued the annual intern doctor's orientation programme, including handbooks and posters demonstrating the correct phlebotomy techniques and order of draw posters, which were distributed to interns and key wards.

Northern Cape

The client liaison officer actively engages clients at all levels. Her duties include training clients at the facility level in relevant laboratory processes, procedures and technology. Lockdown regulations impacted the training programme, and most remote training was conducted. A total of 534 healthcare workers were trained during 186 training engagements.

NATIONAL PRIORITY PROGRAMMES

Prof Wendy Stevens
Director

Dr Pedro da Silva
Operations Manager

INTRODUCTION

The National Priority Programme of the NHLS continued to offer multidisciplinary services to the national diagnostic testing programmes that serve to support South Africa's HIV, tuberculosis (TB), and coronavirus disease 2019 (COVID-19) programmes through the following:

- Ongoing assessment of diagnostic requirements and implementation of programmatic improvements;
- Driving research and development to guide innovations across the laboratory diagnostic value chain;
- Supporting existing testing laboratories through the provision of technical and training assistance; and
- Expanding implementation science to inform improvements in the clinical management of respective diseases and improved linkage-to-care.

Programmatic monitoring and performance, ongoing research, and grant-funded activities conducted in 2021/22 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 Xpert MTB/RIF testing and platforms for more than a decade. In 2017, the programme transitioned to Xpert MTB/RIF Ultra, the more sensitive version of the assay, performed across 173 testing laboratories utilising 433 GeneXpert instruments of varying capacities (232 GX4, 189 GX16, 4 GX48, and 8 GX80 platforms).

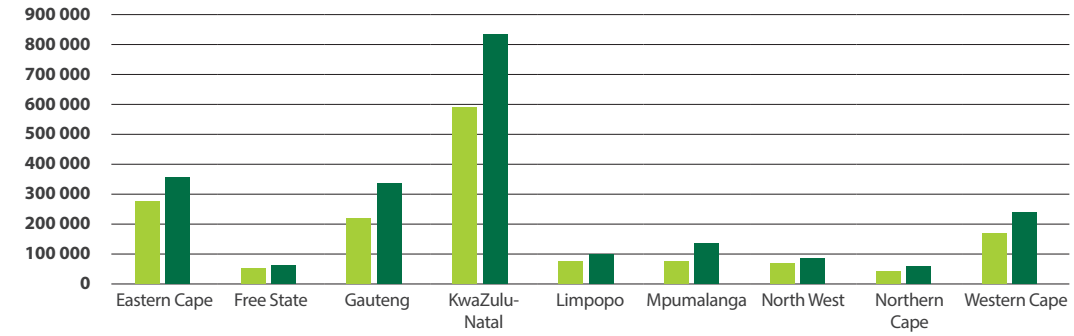
Operations

Since the inception of the programme, 20.9 million tests have been performed, which includes 8.6 million Xpert MTB/RIF Ultra tests. Of these, 2 million cases of TB were identified (9.6%), of which 6% reported rifampicin (RIF) resistance.

Between April 2021 and March 2022, 2 189 319 Xpert MTB/RIF Ultra tests were conducted nationally. The highest number of tests was performed by the following four provinces:

- KwaZulu-Natal: 37.8%
- Eastern Cape: 16.0%
- Gauteng: 15.5%
- Western Cape: 10.8%

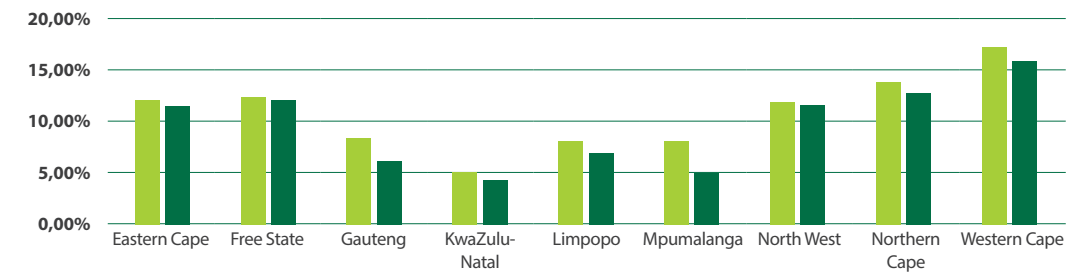
Tested volumes increased by 39% from the previous financial year, where COVID-19 containment measures and various levels of lockdown had greatly impacted the TB programme. During the last quarter of 2021/22, monthly tested volumes surpassed those for the equivalent period, yearly, since 2018.



	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape
2020/2021	278 075	51 480	216 556	584 721	75420	77155	70 103	41 500	169 205
2021/2022	349 324	60 743	338 524	828 480	98 932	134 680	84 751	56915	236 970

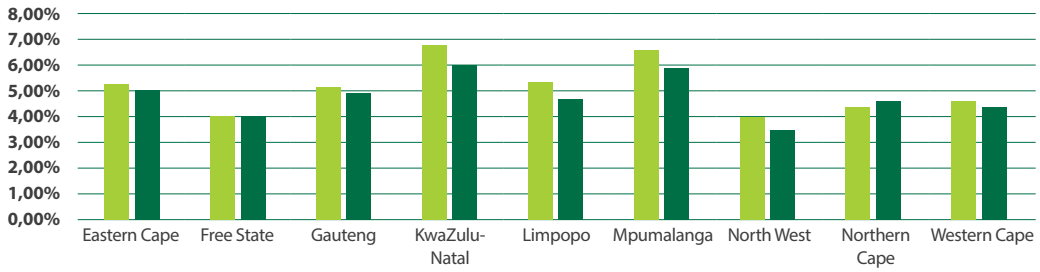
Figure 1: Xpert MTB/RIF Ultra provincial tested volumes for 2020/21 and 2021/22

The average national TB detection rate among those tested was 7.8% (9.1% in 2020/2021). Western Cape reported the highest detection rate (15.8%), and KwaZulu-Natal reported the lowest (4.2%). The trend remains unchanged from 2020/21. The average RIF resistance detection rate for the period was 4.9% (5.1% in 2020/2021). KwaZulu-Natal reported the highest RIF resistance rate of 6.1%, followed by Mpumalanga at 5.9%, while the North West reported the lowest rate at 3.4%.



	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape
2020/2021	11,88%	12,30%	8,35%	5,20%	8,07%	8,05%	11,69%	13,80%	17,24%
2021/2022	11,56%	12,06%	6,04%	4,20%	6,70%	5,35%	11,35%	12,84%	15,81%

Figure 2: Xpert MTB/RIF Ultra provincial positivity rates for 2020/21 and 2021/22.



	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape
2020/2021	5,22%	4,01%	5,11%	6,68%	5,31%	6,54%	3,98%	4,37%	4,53%
2021/2022	5,02%	3,96%	4,78%	6,08%	4,65%	5,89%	3,42%	4,54%	4,33%

Figure 3: Xpert MTB/RIF Ultra provincial rifampicin resistance for 2020/21 and 2021/22.

Tested volumes increased by 39% from the previous financial year, where COVID-19 containment measures and various levels of lockdown had greatly impacted the TB programme. During the last quarter of 2021/22, monthly tested volumes surpassed those for the equivalent period, yearly, since 2018.

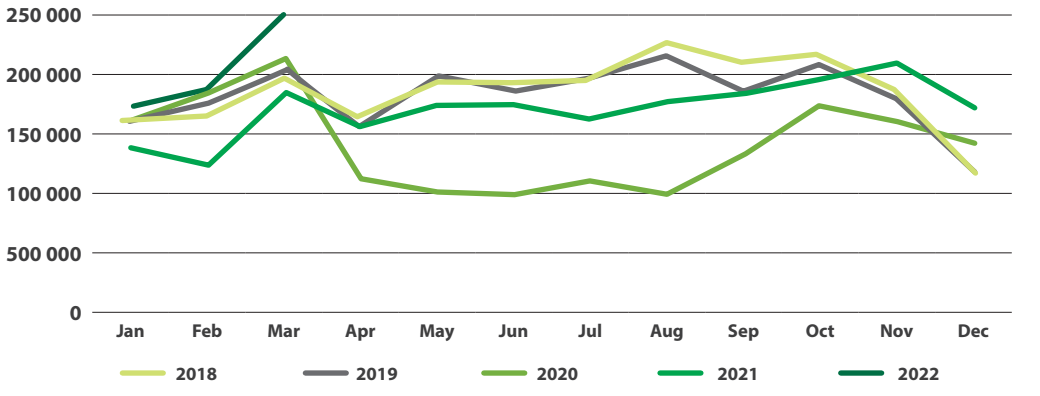


Figure 4: Recovery of Xpert Ultra tested volumes in 2021/22, with the highest numbers conducted during March 2022.

Of all the Xpert MTB/RIF Ultra test results reported in the review period, 1.2% were detected as "trace" (1.6% reported in 2020/21). "Trace" amounts of ***Mycobacterium tuberculosis*** complex (MTBC) represent the lowest measurable level of genetic material detected due to the amplification of specific insertion sequences. Provincial differences were noted, with the Western Cape reporting the highest "trace" detection rate (2.1%) and KwaZulu-Natal reporting the lowest (0.9%). The detection of "trace" has important clinical implications, as it may be representative of the detection of low bacillary load in active TB disease but may also represent the residual detection of nonviable organisms from a previously treated TB episode, thus necessitating further and thorough clinical assessment.

During 2021/22, 94.7% of Xpert MTB/RIF Ultra tests were performed within a turnaround time (TAT) of 40 hours, which exceeded the NHLS Annual Performance Plan (APP) target of 92%.

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

To ensure testing quality, all Xpert laboratories are enrolled in the SmartSpot Quality (Pty) Ltd. external quality assessment (EQA) programme using dried culture spots. Three cycles of EQA were distributed in 2021/22, with 94% of Xpert laboratories submitting results for assessment. Of those submitting assessment results, 93% of laboratories achieved a 100% panel pass rate across the three cycles. The outcome of the assessments is communicated to the Quality Assurance Unit and individual laboratories. Interventions are triggered where performance has not been as expected.

Outputs

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 virtually and provided via www.TBGxMonitor.com. The online training programme comprises six podcast sessions with knowledge assessed upon completion of each module. In 2021/22, 103 laboratory staff completed training.

Good Laboratory Practice training for Xpert testing laboratories was offered online to address specific needs associated with GeneXpert testing.

A workshop, held virtually for 116 GeneXpert operators, focusing on the C360 GeneXpert remote monitoring software, was completed.

On-site, troubleshooting support visits were completed for 26 laboratories. In addition, an NHLS Quality Assurance Auditors training workshop was held to enhance skills to provide troubleshooting support within their respective representative regions.

Xpert Ultra and Xpress SARS-CoV-2 Workshop held for NHLS QA auditors. Puleng Marokane (GeneXpert Programme Manager, far right).

Evaluation of Cepheid's 10-colour GeneXpert module against the existing 6-colour spectrum using the Xpert® MTB/RIF Ultra assay

Cepheid has improved the multiplexing capacity of the GeneXpert instrument to detect a greater number of molecular targets in a single assay by upgrading its optics from a 6- to 10-colour detection system, which also allows the detection of a broader spectrum of pathogens. The GeneXpert module hardware remains unchanged, and the calibration of the original 6-colour channels is impartial to the calibration of the four additional channels.

In 2020, in response to COVID-19, an additional 110 GX4 systems were procured, many with 10-colour functionality. This has made it easier to plan for implementing the Xpert MTB/XDR assay, which requires 10-colour functionality and is a game-changer in the rapid diagnosis of drug-resistant TB.

From a quality assurance perspective, as the Xpert MTB/RIF Ultra assay can operate on either 6- or 10-colour functionality, a comparative evaluation was necessary. Diagnostic performance was demonstrated between the current 6- and newer 10-colour systems when tested with panels comprising four DCS cards each with a known concentration of whole inactivated MTBC or non-tuberculous mycobacterium isolates. The results demonstrated 100% concordance for MTBC detection and identification of rifampicin susceptibility. Operating either system was similar with respect to specimen processing, software navigation, and maintenance procedures. According to the findings, Xpert MTB/RIF Ultra testing can be performed on either six or ten-colour modules. Ten-colour modules are easily differentiated from those with six-colour functionality due to the blue markings present on module doors.

Planning for the implementation of the Xpert MTB/XDR assay

Among people with TB and RIF-resistant TB, additional testing for resistance to at least isoniazid (INH) and fluoroquinolones (FLQs), respectively, should be performed promptly to guide treatment decisions. The World Health Organization (WHO) has recommended using commercially available molecular line probe assays (LPAs) as the initial test to detect resistance to FLQs for people with RIF-resistant TB[1].

LPAs' performance is influenced by smear-positivity status when performed directly off the specimen. Where tests are unsuccessful, the TB culture processed in parallel as part of the testing reflex must be the first flagged positive before the LPA is repeated. Depending on the time taken for the TB culture to flag positive, this may impact patient management and the decision of whether patients should remain on the novel shortened oral regimen or be switched to an alternate regimen.

The Xpert MTB/XDR assay, performed on GeneXpert instruments with 10-colour functionality, is a new assay intended to aid in the detection of drug-resistant MTBC DNA in less than 90 minutes. In specimens where MTBC is detected, the assay can also detect INH resistance-associated mutations, ethionamide resistance associated with ***inhA*** promoter mutations only, FLQ resistance-associated mutations, and second-line injectable drug-associated mutations.

In January 2021, the WHO recommended three classes of nucleic acid amplification tests (NAATs) not previously reviewed[2]. Of the recommendations, the Xpert MTB/XDR assay was the only assay to predict resistance to second-line anti-TB agents. The overall conclusion was that the available evidence supported the use of low-complexity automated NAATs (i.e. the Xpert MTB/XDR assay) for the detection of resistance to INH and second-line anti-TB agents.

The NPP was one of the sites included in the Foundation for Innovative New Diagnostics (FIND) multi-country diagnostic evaluation of the Xpert MTB/XDR assay. Data were published[3] and considered by the WHO in the recent Xpert MTB/XDR recommendations[4]. The assay demonstrated high diagnostic accuracy and met the WHO's minimum target product profile for a next-generation drug susceptibility test.

Owing to Xpert MTB/XDR assay's equivalent performance to the current standard-of-care (LPAs) and its ability to reflex residual-treated specimens directly from Xpert MTB/RIF Ultra RIF-resistant, it will enable rapid extended drug resistance profiling to improve diagnosis and management of drug-resistant TB. Its implementation within the NHLS was approved by the CEO 14 February 2022. The implementation follows a phased approach and will likely be completed in 2022. Considerations for implementation of the Xpert MTB/XDR assay were shared by the team at the 10th South African AIDS Conference's 'Patient-centred diagnostics amid a pandemic' symposium (9–10 June 2021) and at the African Society for Laboratory Medicine's (ASLM) session on 'Innovating for Tuberculosis Diagnostics' (15 July 2021) .

Publications

Experiences on programmatic considerations for the laboratory diagnosis of extra-pulmonary TB by Xpert MTB/RIF Ultra were shared virtually at the 52nd World Conference on Lung Health of the International Union against Tuberculosis and Lung Disease, 19–22 October 2021[5]. Evaluation findings of the Xpert MTB/XDR assay were shared at the same event[6].

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 approval from the United States Food and Drug Administration to support the COVID-19 testing scale-up as a rapid reverse-transcriptase-PCR (RT–PCR) test intended for the qualitative detection of SARS-CoV-2 genetic material from nasopharyngeal, oropharyngeal swab or nasal wash/aspirate specimens.

The NHLS leveraged the existing GeneXpert footprint (primarily used for TB testing) and maximised available spare capacity to include COVID-19 testing. The Xpert platform allows for random access across testing modules, with the Xpert Xpress SARS-CoV-2 assay requiring ~45 minutes to complete. This is considerably shorter than the Xpert MTB/RIF Ultra for TB testing, which results in approximately 135 minutes.

Operations

For the period under review, 1 067 389 Xpert SARS-CoV-2 tests were conducted on the GeneXpert platforms. Testing volumes varied by month, with a monthly average of ~89 000 tests, peaking in August (135 616) and December (131 111) 2021, coinciding with South Africa's third and fourth waves of COVID-19 infections. The detection rate was highest in July and December 2021, at 34.8% and 36.8%, respectively. The lowest detection rates were reported in October and November 2021 at 5.1% and 4.1%, respectively (pre-fourth wave of COVID-19 infections).

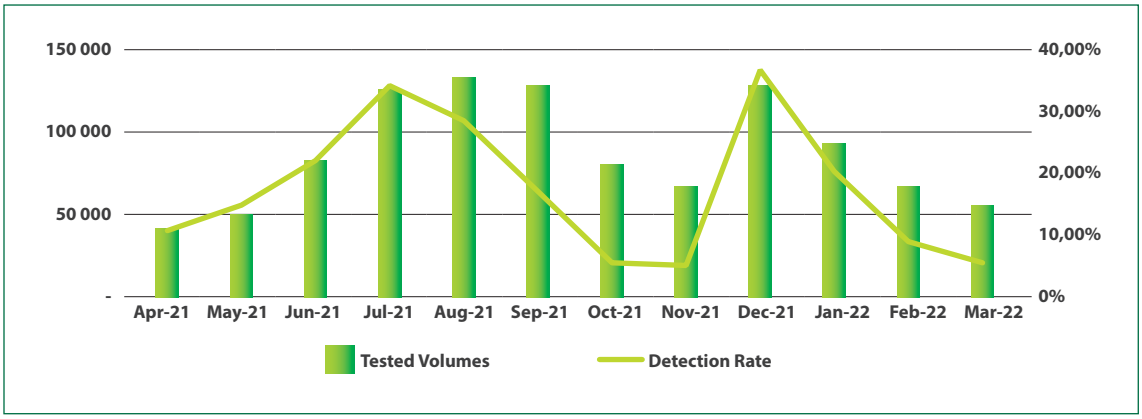


Figure 5: Xpert Xpress SARS-CoV-2 monthly tested volumes and detection rate for 2021/22.

By province, Gauteng and KwaZulu-Natal jointly tested ~42% of all Xpert Xpress SARS-CoV-2 tests. Interestingly, the lowest number of tests conducted was in Limpopo, although they reported the highest detection rate (~34%).

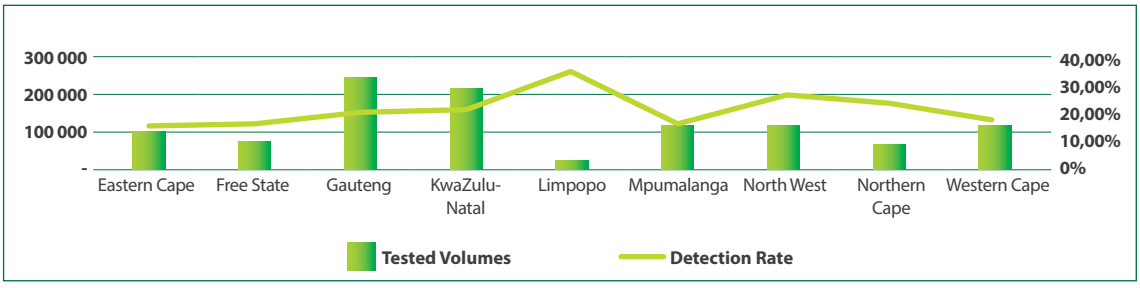


Figure 6: Xpert Xpress SARS-CoV-2 provincial tested volumes and detection rate for 2021/22.

To monitor testing quality, 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 were distributed in the review period, each consisting of four DCS to be tested, with 92.5% of Xpert laboratories submitting results for assessment. Of those submitting, 92.8% of laboratories achieved a 100% panel pass rate across the two cycles. Consolidated reports on laboratory performance were distributed to the NHLS QAD and area managers at the end of each EQA cycle.

Outputs

Training

Through the provision of training, verification of instruments to conduct Xpert Xpress SARS-CoV-2 testing, loading of assay definition files, and interface checks, a further 66 laboratories were initialised for live testing, bringing the total number of laboratories testing nationally for COVID-19, using the GeneXpert platform, to 108. This includes mobile vehicle laboratories based at ports of entry (airports and land borders).

For 2021/22, 224 laboratory staff members were trained on the Xpert Xpress SARS-CoV-2 assay.

Publications

Experience gained from the Xpert Xpress SARS-CoV-2 quality assurance programme, particularly interventions to limit testing contamination, was presented virtually at the 52nd World Conference on Lung Health of the International Union against Tuberculosis and Lung Disease, 19–22 October 2021[7].

NATIONAL DIAGNOSTIC TESTING SERVICES: HIV PROGRAMME

National CD4 Count and Reflex Cryptococcal Antigen Testing Programme

Overview

CD4 testing continues to be a valuable measure of the overall immune status of HIV-infected patients for appropriate patient management, identification of underlying opportunistic infections such as cryptococcal meningitis[8,9,10,11,12] monitoring of late presentation (advanced and very advanced disease) and rapid initiation into care[13,14,15,16]. CD4 data have provided critical programmatic evidence through modelling and monitoring initiation and adherence to therapy[17,18,19,20].

Operations

CD4 testing

The significant decrease of approximately 15% in CD4 test volumes noted in 2020/21 due to COVID-19 restrictions showed some recovery in 2021/22, with a slight annual increase of 3.4% from 2 316 779 to 2 365 683 (55 602 test increase).

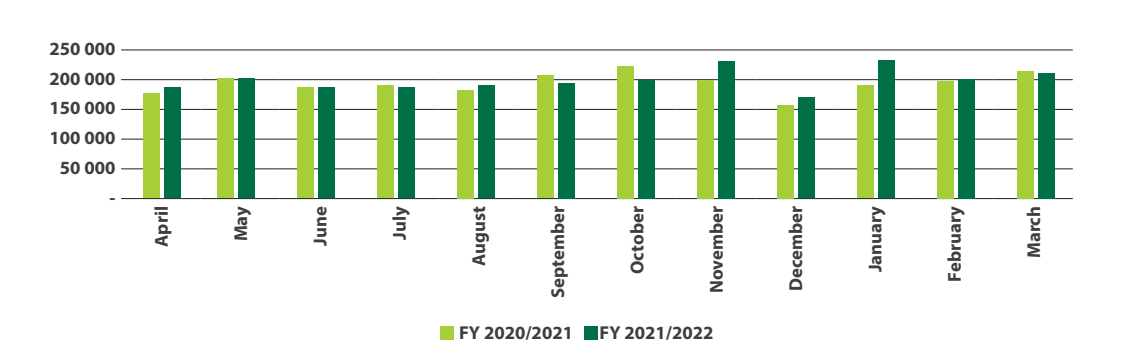


Figure 7: CD4 test volumes per month for 2020/21 and 2021/22.

At the provincial level, the highest increase in test volumes was noted for the Western Cape/Northern Cape region (11%), followed by a 5.6% increase for the Eastern Cape and a slight decrease of 1.78% noted for the Limpopo/Mpumalanga region.

Analyses of CD4 test volumes per CD4 result category demonstrated that nationally, 11.6% of all specimens reported counts ≤100cells/µl (ranging from 5.7% in KwaZulu-Natal to 13.5 and 13.2% in the Eastern and Western Cape regions, respectively). A further 10.5% reported counts between 101-200cells/µl. Specimens with counts between 201-350 and 350-500 cells/µl showed little variability between provinces, with ~17.4% contribution per group to the total number of specimens tested. Specimens with counts >500cells/µl constituted 43.0% (Western Cape/Northern Cape region reporting the lowest at 37.7%).

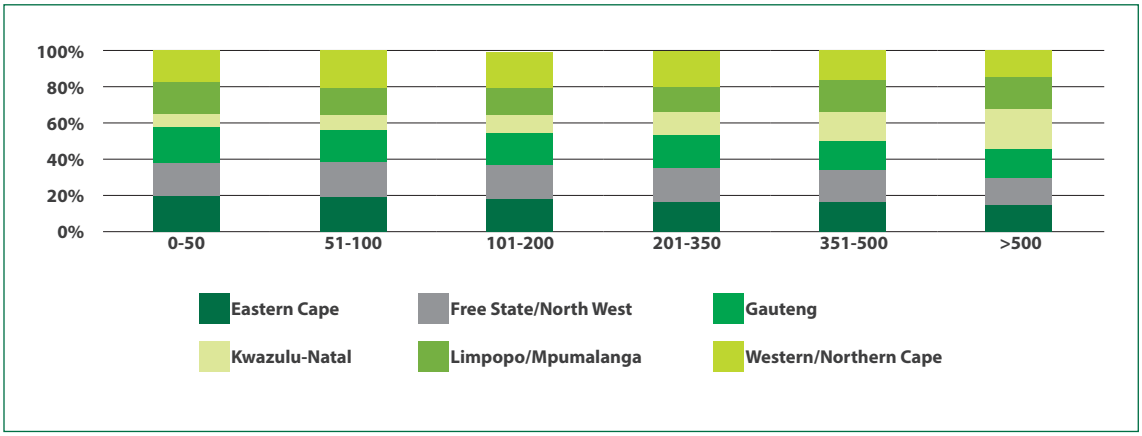


Figure 8: CD4 tests per CD4 category range by region in 2021/22.

Turnaround time data confirmed a national performance of 94% of specimens within the prescribed cut-off of 40 hours, with an average within laboratory TAT (i.e., the testing phase) of 18 hours (ranging from 3-27 hours) across the 47 CD4-testing laboratories.

Cryptococcal antigen testing

Nationally, 11.6% of all CD4 specimens tested reported counts <100cells/µl and thus qualified for a reflexed cryptococcal antigen (CrAg) test. For 2021/22, several CrAg tests followed the CD4 trend, with a slight increase from 213 956 in 2020/21 to 214 215 in 2021/22 (259 additional tests, <1% increase).

Gauteng Province contributed the highest CrAg test volumes (25.9%), followed by 18.5% and 13.8% for KwaZulu-Natal and Eastern Cape, respectively. The cryptococcal antigen detection rate was highest in KwaZulu-Natal at 8.2% (a slight decrease from 9.3% in 2020/21), followed by the Eastern Cape (7.04%), with the lowest rate recorded in the Free State/ North West region (4.71%). The national CrAg detection rate for 2020/21 was 6.4% compared to that for 2021/22 of 6.21%. Individual laboratory CrAg detection rates ranged from 9.6% (KwaZulu-Natal laboratory) to 1.9% (laboratory in the Northern Cape). Overall, 27 of 47 CD4 count laboratories (57%) had a CrAg detection rate less than the national value of 6.2%.

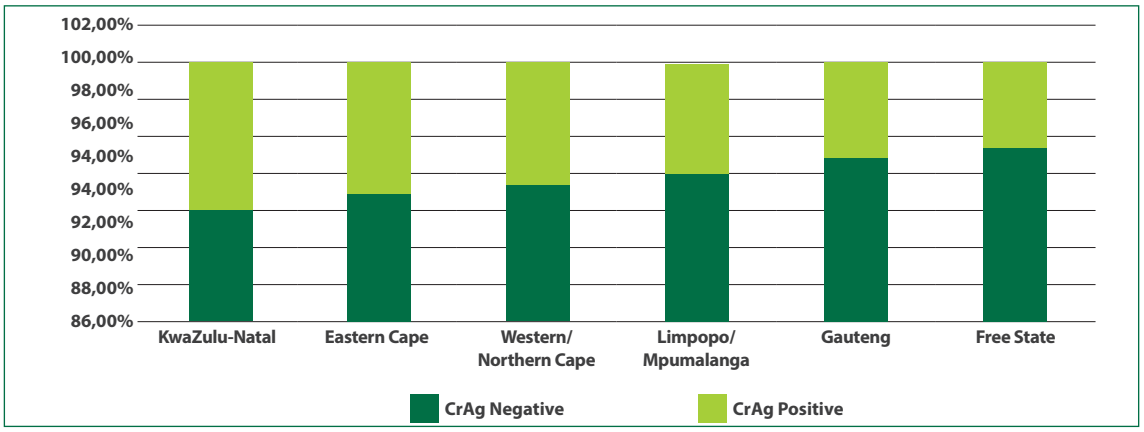


Figure 9: Distribution of the detection rate for cryptococcal antigen by region for 2021/22.

Outputs

Training

The CD4 team provided on-site and/or virtual training for new instrument installations and additional/new staff to ten laboratories, with 25 staff members trained.

Eighteen follow-up and troubleshooting laboratory visits were conducted to assist with identified issues requiring interventions.

The team assisted nine laboratories with instrument verification (either new, replacement, or relocated instruments), and one site audit was conducted to assist the laboratory in preparation for South African National Accreditation System (SANAS) accreditation.

Research

The CD4 team continued with operational research on integrating quality assurance into the NHLS Central Data Warehouse (CDW) for monitoring, TAT, test validations, impact of rural CD4 test facilities, CrAg detection rate distribution, identification of vulnerable populations with high HIV and CrAg incidence, and costing and efficiency exercises of laboratory testing.

Five publications were published in peer-reviewed journals[21,22,23,24,25], and four were first authors.

Four outputs were presented at the 4th Pathology Research and Development Congress (PATHRED), NHLS, Johannesburg in August 2021[26,27,28,29]. An equivalent number of presentations were accepted to the ASLM 2021 Conference, 15-18 November 2021[30,31,32,33].

National HIV Viral Load Testing Programme

Overview

In 2021, it was estimated that South Africa had 8.2 million people living with HIV, of which 4.8 million were receiving anti-retroviral therapy (ARV)[34]. Measurement of the HIV viral load (HIVVL) is the preferred laboratory test for monitoring an individual's response to ARV. The NHLS provides HIVVL testing at 17 centralised laboratories across eight provinces in support of the national HIV Programme. Similar to the trend seen in 2020/21, the HIVVL testing programme was relatively unaffected by the COVID-19 pandemic.

Operations

During 2021/22, 6 095 467 million tests were performed, compared to 5 817 529 million during 2020/21, constituting an increase of 4.5% (264 360 tests). 87.7% of these met the WHO definition of virological suppression (<1 000 copies/mL). Using the lower limit of <50 copies/mL, viral suppression was indicated in 71.18% of tests.

Monthly test volumes varied between 374 293 and 572 317. Regionally, KwaZulu-Natal processed the highest percentage of VL tests at 29.6% (1 805 329), followed by Gauteng at 23.4% (1 428 330). The Northern Cape performed the lowest number of HIVVL tests, contributing 1.2% (77 564).

In collaboration with CDW, the team continuously analyses and reviews the national HIVVL programme. Weekly and monthly test volumes and TATs are monitored to identify issues and gaps, assure prompt corrective actions, and strengthen the national laboratory network service. Continuous assistance and frequent onsite visits help to bolster these efforts. Standardisation is ensured across the 17 testing laboratories through the use of national standard operating procedures (SOPs).

Participation in the Quality Control for Molecular Diagnostics and the Centers for Disease Control and Prevention (CDC) NHLS HIVVL EQA programme is a requirement for all 17 laboratories.

Significant challenges were experienced on Abbott's Alinity m instruments, a relatively new untested technology in the programme, awarded under tender RFB017/18-19. Ongoing monitoring, training, and support, coupled with software improvements and continuous updates, via technical service bulletin updates resulted in a notable improvement in laboratory performance. For the period under review, TAT improved dramatically to 93.42%, exceeding the NHLS APP target of 80% of specimens being processed within 96 hours. The TAT targets were exceeded as the implementation of the tender process was completed early in 2021, despite restrictions imposed by the COVID-19 pandemic. The tender implementation may compromise TAT targets as a result of the following activities:

- Based on the tender award, switching suppliers and instrumentation,
- Laboratory renovations to accommodate new instruments,
- Instrument setup and verification
- Referral of testing to alternate sites during renovations/setup, etc.

Similarly, software upgrades to the Roche Cobas systems were instituted to improve instrument performance. The testing capacity was increased with additional instruments installed at the Addington, Edendale, Tshepong and Nelson Mandela Academic laboratories. The current HIVVL tender will expire in June 2022, and preparations are being made to initiate a new tender process.

Outputs

Training

The team provided continual training for both new and existing staff members in need of refresher courses. Super-user workshops are held to further equip laboratory staff with troubleshooting abilities. Two successful super-user workshops were run in 2021/22. The Abbott Alinity m users were hosted at a super-user workshop held at Tygerberg Virology laboratory (1-3 February 2022), while the Roche Cobas super-users workshop was held from 14 to 18 March 2022 at the Roche Scientific Campus in Midrand, Johannesburg.

Abbott Alinity m super-user training, Tygerberg Virology. Somayya Sarang, HIV Viral Load Programme Manager, second from the left.

Roche Cobas super-user group trained at the Roche Scientific Campus, Midrand, 14-18 March 2022.

Pre-analytical track systems

After substantial remodelling and renovations, the pre-analytical track system was successfully installed at the Universitas Academic Virology laboratory. The track system is expected to go live by April 2022.

Pre-analytical track systems were installed at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Mankweng, Rob Ferreira, and Ngwelezane laboratories in the previous financial year.

Performance monitoring

HIV viral load monitoring dashboards provide real-time statistical data for quality improvement purposes. Real-time access to these data has several advantages, including making fast and informed decisions.

A programmatic dashboard was developed by the team utilising Power Business Intelligence as a data analytics platform. Software licences were purchased for each of the 17 HIVVL laboratories and are being assigned.

Supplier dashboards for real-time instrument monitoring are in development. An Abbott Middleware Solution pilot project is underway in KwaZulu-Natal.

Disaster recovery plan

A catastrophic fire at CMJAH (April 2021) resulted in the closure of the largest HIVVL laboratory in the country for three weeks, drawing renewed attention to the risks of highly centralised services and the need for effective disaster management. Consequently, a new HIVVL laboratory was established at Tambo Memorial Hospital to support Gauteng's HIVVL services, and a revised HIVVL disaster recovery plan was drafted.

Regional laboratory systems strengthening

Laboratory Systems Strengthening Community of Practice (LabCoP), a division of ASLM, aimed aims to strengthen laboratory systems through information sharing, tools and resources that support clinical, policy, technical, scientific and programmatic aspects to aid in the successful implementation of HIVVL testing is represented by Dr Lucia Hans (clinical virologist), Somayya Sarang (national HIVVL Programme Manager) and Dr Naseem Cassim (monitoring and evaluation expert). The fifth annual meeting was held virtually from 1-3 December 2021. The theme for 2021 was 'Strengthening Laboratory Systems, Viral Load and Other Essential Testing in the era of COVID-19'.

5th LabCoP Virtual Annual Meeting, attended by Somayya Sarang, Dr Naseem Cassim, and Dr Lucia Hans.

National Early Infant Diagnosis HIV PCR Testing Programme

Overview

Prevention of mother-to-child transmission (PMTCT) of HIV is essential to attaining the global goal of ending the AIDS epidemic. In 2020, the Joint United Nations Programme on HIV/AIDS reported an increase in South Africa's mother-to-child transmission rate from 3,3% to 3,9%[35]. The leading cause of this increase may be poor HIVVL monitoring during pregnancy and breastfeeding.

A new tender for early infant diagnosis (EID) diagnostic assays was advertised in 2021, subsequent to the conclusion of the previous tender award. The outcome of the new tender is pending.

Operations

In 2021/22, 705 980 HIV EID PCR tests were performed, up from 674 068 in 2020/21 (a 4.73% increase). The monthly testing volumes ranged from 54 412 to 65 551, with KwaZulu-Natal processing the majority of tests (26.3%, 189 208), followed by Gauteng (23.7%, 166 805). The Northern Cape reported the least number of tests, with only 1.4%, 10 059. The detection rates were lower, 1.41% in 2021/22 compared to 1.48% in 2020/2021.

Extracted EID data is used to monitor and evaluate the national EID programme. All HIV PCR-positive babies may be traced rapidly using "Reports for Actions" lists generated by the NICD.

The Missed Diagnostic Opportunities report enables meticulous monitoring of specimen rejection rates and aids in the prioritisation of training activities aimed at reducing specimen rejection rates. Consistent facility support visits and mentoring help to lower rejection rates and increase HIV PCR testing uptake.

According to the PMTC guidelines, all healthcare workers must supply one of two special electronic gatekeeping (eGK) permission codes for every HIVVL test requested throughout pregnancy, delivery, and breastfeeding[36]. The specific eGK permission codes allow HIVVL testing without gatekeeping cancellation and tracking of maternal HIVVL testing frequency and suppression rates. The two codes are 'C#PMTCT' if HIVVL is requested during pregnancy and breastfeeding and 'C#DELIVERY' if requested during labour and delivery. Regardless of whether the system rejects the test, the codes should always be entered into the laboratory information system (LIS), allowing monitoring of maternal HIVVL performance and suppression.

Output

Training

Sister Tsakani Mhlongo conducts training for healthcare workers (HCWs) involved in the management of newly born babies and infants, and the training is targeted at clinicians, nursing staff, counsellors and facility managers. Training activities include:

- Reinforcement of guidelines and any updates;
- Mentoring, guidance and support of trained HCWs;
- Identification of babies/infants who require testing;
- Promoting confirmatory PCR test uptake at two time points: 6 months and below 2 years;
- Correct administration of NHLS request forms;
- Collection of quality specimens to maximise HIV PCR diagnosis and minimise specimen rejection;
- Interpretation of rapid and HIV PCR results;
- Management of discordant PCR results; and
- Management of those exposed to HIV infection in terms of appropriate ARV prophylactic regimens.

In 2021/22, 1 287 healthcare workers were trained, and 185 healthcare facilities were supported.

Facility file audits being conducted by Sr Tsakani with Region G Sub-district HAST Manager and ANOVA Technical Adviser at Mountain View Clinic. Sr Tsakani, far left.

National HIV Drug Resistance Testing Programme

Overview

There are five NHLS HIV drug-resistance testing laboratories located throughout South Africa: CMJAH (servicing Gauteng), Tygerberg (servicing Western and Eastern Cape), Inkosi Albert Luthuli Central Hospital (IALCH, servicing KwaZulu-Natal), Universitas (servicing Free State and North West), and Dr George Mukhari (DGM) (servicing northern Gauteng, Limpopo and Mpumalanga).

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-based regimen, provided that patients have been exposed to dolutegravir for at least two years and meet the definition of confirmed virological failure.

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

Operations

Across all laboratories, 4 549 specimens were processed for HIV drug-resistance testing in 2021/22, a 9% increase from 2020/21.

Three laboratories, CMJAH (33%), Tygerberg (28%), and IALCH (21%), processed the bulk of the testing volumes. CMJAH serves as a backup laboratory for DGM, where no testing has been performed since November 2021 due to problematic equipment, explaining the higher proportion of tests performed at CMJAH.

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

Output

Standardisation

A commercial HIV drug-resistance kit was validated and implemented; this implementation standardised HIV drug-resistance testing nationally. A new kit combining all relevant target genes, including integrase, is under validation and will be implemented for further standardisation should the validation be successful.

National NHLS HIV Drug-resistance Committee

Dr Kim Steegen, a senior medical scientist, continued to chair the committee in 2021/22. The committee guides best practices and aims for standardisation across the diagnostic service.

Publications

Three publications were published in peer-reviewed journals[37,38,39], and two were first authors. Three research abstracts were presented orally at the 11th IAS Conference on HIV Science 18-21 July 2021[40], 29th International Workshop on HIV Drug Resistance and Treatment Strategies, 6, 13, 20 and 27 September 2021[41], and 6th Annual ECSACOP Scientific Conference, 17-18 December 2021[42]. A poster was accepted at the PathRed 2021 conference held on 19-21 August 2021[43].

National HIV counselling/testing and TB campaigns and events

Overview

Previously, the NHLS supported World AIDS Day and World TB Day commemorations throughout South Africa with the deployment of Xpert testing mobile laboratories to provide onsite molecular diagnostics for TB testing.

Due to the COVID-19 pandemic, commemorations of both national World TB Day 2020 and World AIDS Day 2021 were cancelled.

In 2022, Deputy President David Mabuza (in his capacity as the Chairperson of the South African National AIDS Council) led the commemoration of World TB Day (24 March 2022) in Barkley West, just outside Kimberly in the Northern Cape. The NHLS was one of the participating organisations and assisted in the fight against TB. The NHLS, partnering with the DoH, conducted road shows and testing using the NHLS mobile laboratories, visiting communities, particularly the most isolated and conducting TB screening and onsite testing.

NHLS staff members involved in planning, logistics, and testing in support of national World TB Day, Northern Cape.

NHLS medical technologist processing specimens in the mobile laboratory, World TB Day 2022.

LINKAGE-TO-CARE AND DATA MANAGEMENT FOR PROGRAMMATIC MONITORING

National Laboratory Results SMS Printer Programme

Overview

SMS printers are placed at 2 232 primary and community health care facilities across South Africa in all 52 districts where patients are being initiated on ART. The rationale for this deployment was to facilitate the rapid delivery of results for same-day ART initiation. Originally, the SMS printers reported a limited test result repertoire, reporting only smear microscopy results for the presence or absence of acid-fast bacilli. Over time, this repertoire has increased to include additional results for TB (Xpert MTB/RIF Ultra), core HIV testing (CD4, HIVVL, HIV EID PCR), ART monitoring (creatinine clearance and hepatitis B surface antigen) and advanced HIV disease (reflex CrAg). Any amended results from those listed and notifications of rejected specimens are also relayed via SMS printers.

SMS printers operate bi-directionally: results are pushed but can also be retrieved when HCWs scan the respective NHLS barcodes. The bi-directionality aims to improve the rapid delivery of priority diagnostic results throughout South Africa.

The majority of SMS printers are based on the global data service platform (GDSP), which can be easily deployed in multiple settings requiring minimal customisation. One of the benefits of GDSP is that communication is more secure and efficient than conventional technology. GDSP SMS printers generate an automated heartbeat message that regularly transmits the binary and quantitative information that is sent to a national server that allows for the remote monitoring of the performance and utilisation of each printer.

Operations

The national printer platform provides substantial coverage for HIV/TB result delivery to healthcare facilities. However, with the scale-up of ART services to all 3,800 healthcare centres, there is a gap of 1 568 facilities where printers have not been deployed.

During 2021/22, 8 893 210 results were successfully delivered to healthcare facilities through this mechanism.

To strengthen the platform performance monitoring, two additional quality indicators will be introduced in the last quarter of 2022/2023: monitoring connectivity signal strength and TAT for result delivery.

Data Management and Programmatic Monitoring

Overview

During 2021/22, data analysis for programmatic monitoring and evaluation purposes continued with the generation of an array of monthly, quarterly, and ad hoc reports for distribution to partners, funders, TB/HIV coordinators, and provincial and national DoH. The reports provide aggregated/non-patient identified data on test volumes, detection rates, TAT, error rates, specimen rejection rates, and exception reporting, such as tests with CD4 counts under 100 cells/µl and HIVVL counts of <1 000 copies/ml.

Programmatically, data is used to analyse laboratory workflows 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 is utilised to confer numbers reported in TB registers and assist in reducing the number of patients lost to follow-up.

Data outputs complied with ethics requirements under the Wits Human Research Ethics Committee, Clearance M160978 (expired 11 December 2021) renewed as Clearance M2111144 (valid to 1 December 2026).

Outputs

Business intelligence dashboards

Although needed, the provision of periodic "static" reports prevents timeous critical decisions due to data provision not being real-time or on-demand. This may translate to targeted interventions for disease hotspots and or staffing/ resource/workforce planning not being actioned proactively.

To address this gap and increase access to "self-service" access to real-time/on-demand data, several use cases were adopted to provide the current solutions that are in various stages of the development cycle, i.e., "in staging" and/or "in production". Using Power Business Intelligence, 22 automated dashboards are under construction (one for each of the HIVVL testing laboratories and six HIV and TB programmatic dashboards). These dashboards are provisioned daily and are only a single day in data arrears. The aim is that these solutions will enhance existing programmatic databases to improve the quality of current metrics and allow for a near real-time view of the end-to-end process/cycle from the time a patient specimen is collected (at the facility) to when the result is provided to the patient.

Security is ensured, as the solutions will only be shared with authorised users that belong to a pre-approved distribution group without the ability of users to share information with colleagues outside of the distribution group. In addition, the underlying dataset is not accessible to users who only have read and access rights to protect against misuse of the same.

In 2021/22, five dashboards moved from the development phase to 'staging':

1. HIV TAT daily dashboard: will allow access to HIVVL operational information and provide visibility of the programme's key performance indicators (daily volumes and TAT) in near real-time;
2. HIV programmatic dashboards – Operational view: to assist operational management in tracking areas not reaching desired service level agreement targets for CD4, EID, HIVVL and CrAg) in near real-time;
3. HIV programmatic dashboards – Management View: to assist executive management with visibility into business performance for CD4, EID, HIVVL and CrAg) in near real-time;
4. Rejections dashboard: will allow understanding and provide reasons behind rejected specimens and frequencies to inform daily decisions on reduction of these; and
5. HIV CrAg dashboard: will allow access to a comprehensive snapshot of daily volumes, outcomes, and TATs by geographical distribution, laboratory and time factors.

Improving the laboratory value chain: leveraging digital technology

eLABS: eLABS (an electronic laboratory specimen tracking and tracing tool) was initially developed (EQUIP Health) for scaled HIVVL testing in Zambia.

As of March 2021, eLABS has scaled to over 1 103 facilities in Zambia and 2 068 facilities in South Africa, with 392 100 HIVVL tests processed in Zambia and >2.2 million in South Africa. Of these, 100% were authorised/released in both Zambia and South Africa. The average result of TAT was 24 days in Zambia and 2.5 days in South Africa. The HIVVL suppression rate was 94% for Zambia and 73% for South Africa. A total of 85% of actionable results (unsuppressed patients, invalid results and rejected specimens) were read/acknowledged by healthcare workers in Zambia and 65% in South Africa.

On 24 July 2020, eLABS rolled out its COVID-19 module in South Africa to support the SARS-CoV-2 pandemic. In this reporting period, 384 336 RT–PCR tests were processed through eLABS with a 10% detection rate.

The SARS-CoV-2 antigen rapid diagnostic test module was subsequently developed to support the point-oftesting sites in South Africa. However, the NHLS COVID-19 Surveillance Application (CSA) and TrakCare remained the primary points of data collection.

eLABS is now being piloted in Mozambique (in Portuguese), with Liberia to follow suit.

Research and Development to Support the National Programmes

Overview

The Research and Development (R&D) group comprises a multidisciplinary team specialising in applied research, translational and implementation science of new laboratory diagnostics for HIV, TB and COVID-19. The team is experienced in performing laboratory and clinical evaluation trials of new laboratory and point-of-care diagnostics and innovations across the pathology value chain and the development of quality (reference) materials. The R&D team comprises specialists in data science, digital health and geographic information system (GIS) mapping. Under the leadership of Professor Lesley Scott, the group outputs contribute to:

- The adoption and improvement of services within the NHLS and within the context of COVID-19 included collaborating with the South African Health Products Regulatory Agency (SAHPRA) for COVID-19 assay evaluations for performance recommendations;
- Transfer of knowledge and implementation support to the NPP;
- Policy and guideline development for the DoH
- 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-changing technologies. The primary work streams in the iLEAD portfolio are HIV, TB, COVID-19 and cross-cutting innovations, which fall within the digital health space and are used across the laboratory value chain. The R&D team is also supported by the National Institutes of Health (NIH), European and Developing Countries Clinical Trials Partnership (EDCTP) (in collaboration with FIND) and South African Medical Research Council (SAMRC) funding for innovations in TB and COVID-19 diagnostics and data science for impact.

The R&D work streams specialise in innovative technology landscape reviews and, through well-defined target product profiles, identify relevant technologies for evaluation. An evaluation framework will include developing and sourcing reference materials and testing panels, developing robust laboratory and clinical trial protocols in collaboration with partners, and management according to good clinical laboratory practice. Biobanking, biorepository and developing tailored quality assurance programmes are included.

Skill sets within the team include molecular medicine, genomics, immunology, bioinformatics, health economics, epidemiology, and big data analytics, along with core skills in diagnostic project management. The team also drives a postgraduate research agenda to support BSc (Hons), MSc, PhD and undergraduate medical student projects.

Outputs

Addressing the COVID-19 pandemic

SARS-CoV-2 diagnostic evaluations: Between April 2021 and March 2022, the R&D group continued to evaluate new SARS-CoV-2 diagnostics (molecular, serology,and antigen) through the iLEAD programme in collaboration with the NHLS and SAHPRA.

The evaluation pipelines were further extended to include assessments of the impact of variants of concern on assays (in use) and variant typing assays, as well as developing usability protocols for evaluating antigen self-tests.

During this time, an additional 65 assays (total since April 2020, 180) were evaluated, and 41 (total since April 2020, 89) were recommended for use. This also included a clinical trial in collaboration with the Desmond Tutu Health Foundation (Prof Linda-Gail Bekker) performed across three provinces to evaluate the Abbott PanBio rapid antigen assay in field settings.

The instrument-based SARS-CoV-2 rapid antigen assay from LumiraDx was also evaluated by the R&D team, who further assisted the NPP with training materials and support for national implementation.

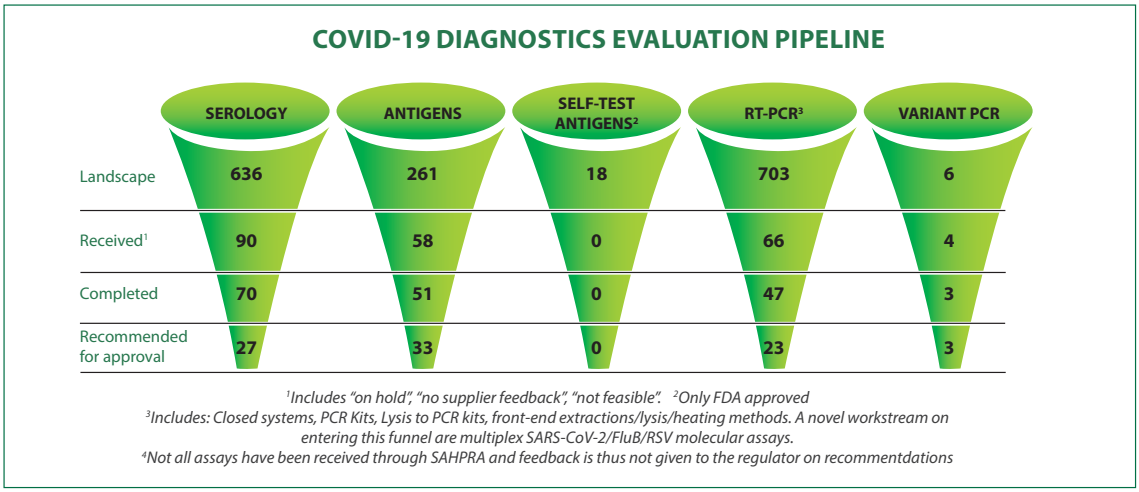


Figure 10: COVID-19 diagnostic evaluation pipeline for serology, antigen and PCR assays conducted by the R&D team.

The experience gained by the R&D team through the multiple COVID-19 evaluations performed also culminated in an extension of the iLEAD project to investigate a new ultra-high throughput molecular technology. The team visited the Northwell Health Laboratory in New York in March 2022 for technology review and installation planning as well as discussion on alternative use cases for COVID-19 self-collection.

The R&D team continued to provide support to the priority programme laboratories performing SARS-CoV-2, rapid antigen and COVID-19 antibody testing. The evaluation panels were also used by the NPP to investigate quality testing on several closed platforms.

Data analytics for continuous quality monitoring and epidemiology of COVID-19: The R&D data team leveraged their TB data analytics skills to support the NPP and vaccine partners in COVID-19 data analytics for continuous quality monitoring of laboratory diagnostics under funding from the SAMRC.

The cycle threshold (Ct), a continuous variable of PCR tests, is used as an added epidemiological marker. Data updates were shared with the Virology Expert Committee (VEC) and nationally through the scientific community (variant, genomics and Ministerial Advisory Committee groups) in the form of weekly briefs.

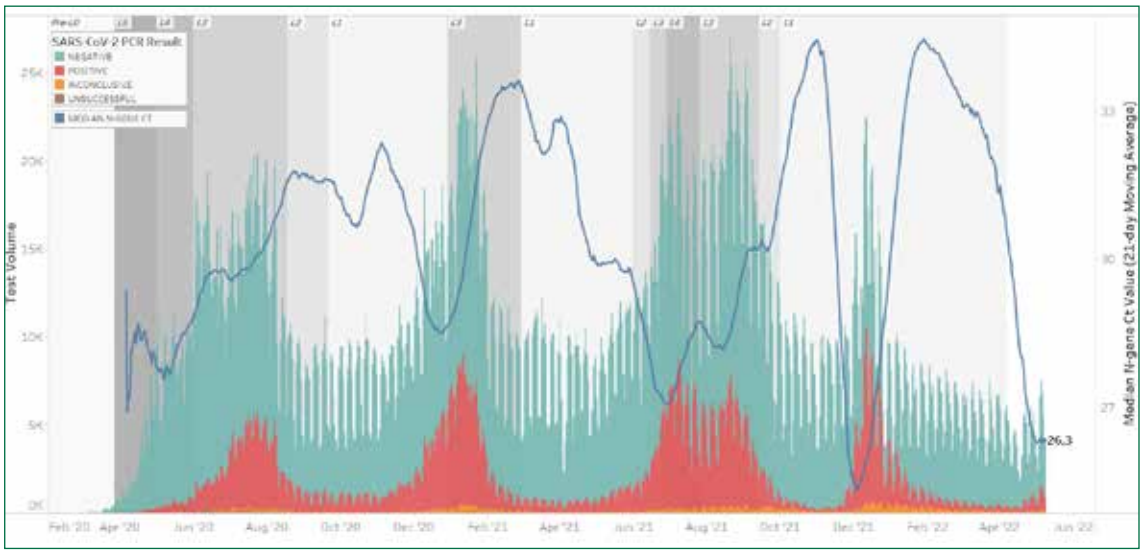


Figure 11: NHLS laboratory testing profile of 7.9 million-episode numbers and Ct values. Red bars (positive tests). Blue line (median N-gene Ct values). Lockdown levels are indicated.

GIS mapping between COVID-19, HIV and TB diagnostic variables was ongoing to support the NPP with operations and the Ministerial Advisory Committee on syndemic disease (HIV/TB/COVID-19) control.

Contributing to Africa's Innovation through Science: Verification and External Quality Assurance Programmes

Xpert MTB/RIF EQA and Verification Programme: Continuous engagement and provision of scientific and technical support to SmartSpot Quality Pty (Ltd), a Wits Enterprise spin-off company initiated by the group.

National and international laboratories are supplied with DCS technology for verification and EQA of GeneXpert MTB/RIF and GeneXpert MTB/RIF Ultra (Cepheid, Sunnyvale, CA, USA) platform and LPAs EQA Programme comprises the GenoType MTBDR***plus*** and GenoType MTBDR***sl*** (Bruker-HAIN diagnostics, Nehren, Germany) EQA and the Strip Interpretation Analysis programmes.

MTB Lipoarabinomannan (LAM) EQA: The team continued their work on developing a quality material and programme to support the testing of LAM in both clinical (point-of-care) and laboratory settings, with funding support from Wits University.

HIV Viral Load Programmes: The HIVVL thermostable EQA material developed by the team continues to be supplied by SmartSpot Quality Pty. (Ltd) through technology transfer. The R&D team continued to engage and provide scientific and technical support.

COVID-19 reference panels for technology evaluation: The R&D team continued to engage the VEC throughout the COVID-19 pandemic to collect residual clinical material for the development of evaluation panels for COVID-19 rapid antigen and SARS-CoV-2 molecular diagnostics. Clinical trials are ongoing to develop serology panels from COVID-19 convalescent individuals for the evaluation of new serology diagnostics. SARS-CoV-2 viral culture panels received from Prof Bavesh Kana (DST/NRF Centre of Excellence for Biomedical TB Research) and Prof Wolfgang Preiser (Medical Virology, Faculty of Medicine and Health Sciences, University of Stellenbosch) were further developed to measure the precision and limit of detection of SARS-CoV-2 molecular and COVID-19 antigen tests under review for SAHPRA.

Contributing to National Health TB Policy

Aiming for improvements in the sensitivity of TB molecular diagnostics: Several novel TB diagnostics were evaluated by the R&D team, either in laboratory evaluations or full clinical trials. The technologies investigated were as follows:

1. *Xpert MTB/XDR (Cepheid):* A multicentre clinical trial, in collaboration with the FIND, was performed in Eastern Cape Province to evaluate the novel Xpert MTB/XDR cartridge (Cepheid, Sunnyvale, CA, USA) that detects further TB drug resistance targets. This evaluation contributed to the WHO policy on molecular diagnostics and led to a further evaluation performed at two sites in South Africa (Port Elizabeth and University of Cape Town) in 2021/2022 through funding received from EDCTP. Enrollment was completed with 391 participants. Next-generation sequencing is underway, with outcomes contributing to the NHLS implementation model;

2. *Molecular TB multiplatform evaluation:* A head-to-head evaluation commenced in 2018 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 (Cobas MTB) (Roche Molecular, Pleasanton, CA, USA), FluoroType MTBDR (Hain Lifescience/Bruker, Nehren, Germany), Real-Time MTB and Real-Time MTB RIF/INH Resistance (Abbott Molecular, Abbott Park, IL, USA), Becton Dickinson MAX™ MDR-TB (Becton Dickinson, Franklin Lakes, NJ, USA) and Xpert MTB/RIF (Cepheid, Sunnyvale, CA, USA). The completed Phase 1 (laboratory strain analytical evaluation) outcome contributed to WHO endorsement of molecular technologies, and Phase 2 (multi-country clinical evaluation) commenced only with Roche MTB and Hain Lifescience/Bruker Fluorotype assays in comparison to standard-of-care (Xpert MTB/RIF Ultra). Participant recruitment ended 31 May 2021. The study close-out meeting was held in February 2022, and data analysis will commence once the sites in India complete recruitment;

3. *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 ***Mycobacterium tuberculosis*** infection from a human capillary finger stick or venous whole blood. A clinical evaluation of the cartridge, in collaboration with Cepheid, was performed by the team. Participant recruitment ended in November 2021, and preliminary findings were presented at the 52nd World Conference on Lung Health of the International Union against Tuberculosis and Lung Disease, 19-22 October 2021[44].

Ensuring a TB biobank for ongoing evaluations: MTBC-positive isolates with varying mutation patterns continued to be processed for long-term storage at -80°C. The R&D team established a protocol adapting MTBC growth and storage to the MicrobankTM platform (www.https://pro-lab.com/products/clinical-microbiology/bacteriology/microbank/), which is now implemented within their clinical trial protocols. The microbank provides up to 25 cultures compared to one with previous storage protocols.

Alternative specimen collection to improve TB diagnosis: Two approaches are being investigated using a graduated sputum jar (in collaboration with a local manufacturer, Sinapi, Cape Town) to ensure that patients provide adequate volumes of sputum, and optimal buffer volumes are added to sputum in the laboratory. This is being investigated in collaboration with the NPP at Chris Hani Baragwanath Hospital. A second approach is the collection of tongue swabs. This is being investigated through the iLEAD programme in the Hillbrow Community Health Clinic. Both HCW- and self-collected swabs are being investigated for the diagnosis of TB using different molecular platforms. The optimal transport and storage conditions are also being investigated. Swabs are also being investigated in collaboration with the Perinatal HIV Research Unit (Prof Neil Martinson), where the R&D team developed a swab-capture method to co-test for TB and COVID-19 off single sputum. Additional study objectives are to determine i) whether an early morning swab demonstrates superior performance for MTBC detection compared to a spot swab; ii) whether a combination of two swabs (collected at the same time point) increases the yield of MTBC; and iii) whether a combination of a swab and a sputum specimen improves the detection of MTBC.

Data analytics for global disease control: Two main funding streams supported the R&D data team in developing data analytical tools to mine TB laboratory diagnostic data: NIH (R21)-funding in collaboration with Boston University to develop 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; and Newton Medical Research Council/SA/UK to investigate the mapping of molecular characteristics from the Xpert MTB/RIF and Xpert MTB/RIF Ultra across districts in South Africa. Both projects support the NPP with the development of dashboards for operations and disease control. The Newton project ended in 2020 but led to the group receiving additional funding from SAMRC and applying this TB data analytics knowledge to COVID-19.

Publications

Based on R&D activities in 2021/22, sixteen publications were accepted in peer-reviewed journals, three as first authors. Two of these detailed the SARS-CoV-2 omicron variant[45,46]; a comparison of the physiochemical properties of various nasopharyngeal swabs for COVID-19 detection[47]; five addressed immunoassays for diagnosing COVID-19[48,49,50,51,52]; COVID-19 antibody responses[53]; and self-sampling for SARS-CoV-2 detection[54]. Focusing on TB, three publications were accepted related to the diagnostic performance of new assays[55,56,57], and two were reviews of TB programme indicators[58] and diagnostic testing[59]. Findings of a mHealth solution for improving HIVVL suppression management were also published[60].

Accepted abstract presentations included one at the International AIDS Society Conference, Berlin, Germany, 18-21 July 2021[61]; five at PathRed 2021, 15-18 August 2021[62,63,64,65,66,67,68]; two at the 23rd Annual Conference of the European Society for Clinical Virology, 15-17 September 2021[69,70]; four at the 52nd World Conference on Lung Health of the InternationalUnion against Tuberculosis and Lung Disease, 19-22 October 2021[71,72,73,74]; and two at the ASLM 2021 Conference, 15-19 November 2021[75,76].

Three invited symposium presentations were delivered: Association of Public Health Laboratories (6 May 2021)[77], SAMED Annual Conference 2021, 19-21 October 2021[78], and ICASA 2021, 6-11 December 2021[79].

ADDITIONAL ACTIVITIES TO SUPPORT THE NATIONAL PROGRAMMES

Centres for Disease Control and Prevention grant-funded activities

eLABS, the project that started as a pilot in Ekurhuleni and Sedibeng districts in 2018, has expanded exponentially to cover all U.S. President's Emergency Plan for AIDS Relief (PEPFAR) supported districts in South Africa across six provinces (Eastern Cape, KwaZulu-Natal, Free State, Mpumalanga, Gauteng, and North West), with the exception of three districts out of 27 (two in Limpopo and one in the Western Cape). eLABS users include facilities HCWs, NHLS drivers (internal and contracted), as well as messengers that carry specimens from the hospitals and gateway facilities to the NHLS laboratories at various hospitals. Tests covered by eLABS include HIVVL, COVID-19 PCR, rapid antigen tests, and Xpert MTB/RIF Ultra, which was the latest addition, launched on 25 March 2022. By the end of March 2022, 2 068 facilities were utilising eLABS.

The HIVVL support team visited and supported the 17 centralised testing laboratories to assist in standardisation and streamlining workflows. Real-time monitoring of HIVVL processing instruments went live at CMJAH for Roche Cobas testing instruments. A similar approach is in development for Abbott's Alinity m instruments.

COVID-19 antigen rapid diagnostic testing training programme

SARS-CoV-2 antigen rapid diagnostic tests (RDTs) are an alternative to the more complex PCR assays. They are simpler to use and provide a point-of-care testing solution, thereby increasing testing capacity and decongesting centralised testing laboratories. As part of an integrated training approach, ASLM collaborated with the NHLS to assist in the rollout of accredited training in South Africa. Initially, ASLM trained 23 Master Trainers in January 2021, of which five in turn, trained 527 Trainer-of-the-Trainers (ToTs) across eight provinces, from February to December 2021. Two hundred and seventy-nine of 527 ToTs received ASLM accreditation. The training was further cascaded to 366 end users during the same period, with 335 of 366 users receiving ASLM accreditation.

Before NHLS Master Trainers embarked on ToT training, all ASLM training material was reviewed and modelled to suit the South African environment. Training videos using the Panbio™ (Abbott) and STANDARDTM Q (SD Biosensor) kits were developed by the R&D team.

In collaboration with the DOH, NHLS, ASLM and Global Fund, training materials were co-branded and developed for the DOH's Knowledge Hub platform in December 2021. To address the fourth COVID-19 infection wave, >1 500 HCWs were trained on this platform. In March 2022, LumiraDx commenced ToT training to support the rollout of LumiraDx instruments.

In January 2022, the Clinton Health Access Initiative (CHAI), in partnership with the DOH and NHLS, commenced end-user training at tertiary education institutions (with a target of 29 institutions) in South Africa. Healthcare workers were the focus group with a target of 191 individuals).

Experience on the COVID-19 rapid antigen training activities were presented at the ASLM Special COVID-19 ECHO Session #52, which took place on 15 March 2022.

ASLM Special COVID-19 ECHO Session #52, Lynsey Stewart-Isherwood: "Reviewing Efforts to Increase Community Access to COVID-19 Antigen Rapid Testing Services: The South African Experience". 15 March 2022.

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ACADEMIC AFFAIRS, RESEARCH AND QUALITY ASSURANCE

Prof Koleka Mlisana
Executive Manager

Introduction

The main objectives of the AARQA Division 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. The division comprises two departments, namely, Academic Affairs and Research (AAR) and Quality Assurance (QA), that are collectively responsible for overseeing the implementation and management of the strategic and operational mandate of the division nationally.

AARQA is responsible for maintaining and establishing effective partnerships with health science faculties at South African medical universities, CUs and UoTs.

In collaboration with the area managers, the QA Department serves to:

- Enhance the NHLS QA systems and processes;
- Maintain and acquire accreditation and certification of the laboratories and support service departments across the country; and
- Manage all NHLS laboratories, some private pathology laboratories and other African and United States of America laboratories' proficiency testing schemes (PTSs).

Academic Affairs and Research Department

The Academic Affairs and Research (AAR) Department is responsible for the teaching, training and research mandate of the NHLS. In collaboration with the medical universities, CUs, and UoTs, the department supports an academic platform staffed with skilled personnel that provides 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 by jointly appointed staff within academic institutions. The aim is to ensure cutting-edge, locally responsive research that focuses on translational research to enhance service platforms and influence health policy.

Medical universities in partnership with the NHLS

- University of Cape Town
- University of the Witwatersrand
- Stellenbosch University
- Walter Sisulu University
- University of KwaZulu-Natal
- University of the Free State
- University of Limpopo
- Mangosuthu University of Technology
- Sefako Makgatho Health Sciences University
- University of the Western Cape
- University of Pretoria

Universities of technology and comprehensive universities in partnership with the NHLS

- Cape Peninsula University of Technology
- Central University of Technology
- Free State Durban University of Technology
- University of Johannesburg
- Mangosuthu University of Technology
- Nelson Mandela University
- Tshwane University of Technology
- Vaal University of Technology

AAR is also responsible for overseeing the management and support of the implementation, monitoring and evaluation of 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 and Innovation;
- Grants Programme Management; and
- Grants' Finance Management

Research, Development and Innovation

Teaching, Training and Research

An amount of R262 517 587.28 was transferred to the NHLS for teaching, training, and research (TTR) during the 2021/2022 financial year. The TTR grant is awarded to the NHLS by the government sector to ensure adequate implementation of the teaching, training and research needs of the NHLS. There has been a noticeable decrease in the TTR amounts given to the NHLS over the last financial year.

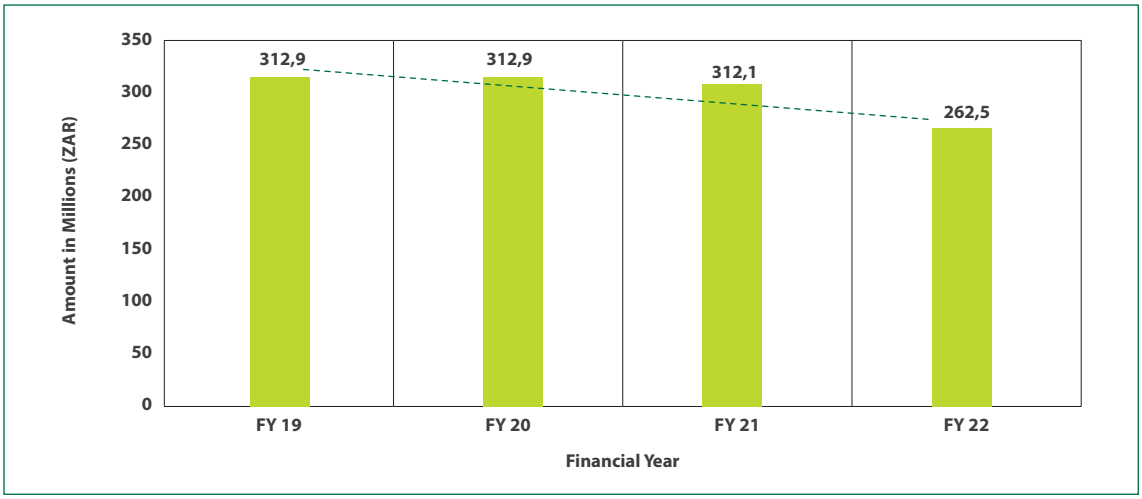

Figure 1: Teaching, Training and Research amounts received by the NHLS for the past four years.

Teaching and training

The delivery of the teaching, training and research mandate of the NHLS is a shared responsibility between the NHLS and medical 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 HPCSA requirements.

Table 1: Current NHLS vocational trainees by discipline as of 31 March 2022

Discipline	Intern: Medical Scientists	Student: Medical Technologist	Registrar	Total
Anatomical Pathology	4	16	75	95
Chemical Pathology	15	2	45	62
Clinical Pathology		202	7	209
Haematology	9	2	53	64
Human Genetics	10	4	5	19
Immunology	11	4		15
Microbiology	21	9	52	82
Oral Pathology			1	1
Virology	25	20	22	67
Other		15		15
Total	**95**	**274**	**260**	**629**

During the 2021-2022 financial year, there were 629 trainees from various academic institutions and disciplines on the NHLS platform. These include 95 intern medical scientists, 274 medical technology students, and 260 registrars. The table above provides more information on the number of trainees in each pathology discipline.

Registrar and Intern medical scientists pass rates

The NHLS is the sole provider of training for 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 II examinations from 41% (2017) to 74% (2021) as depicted in the graph below.

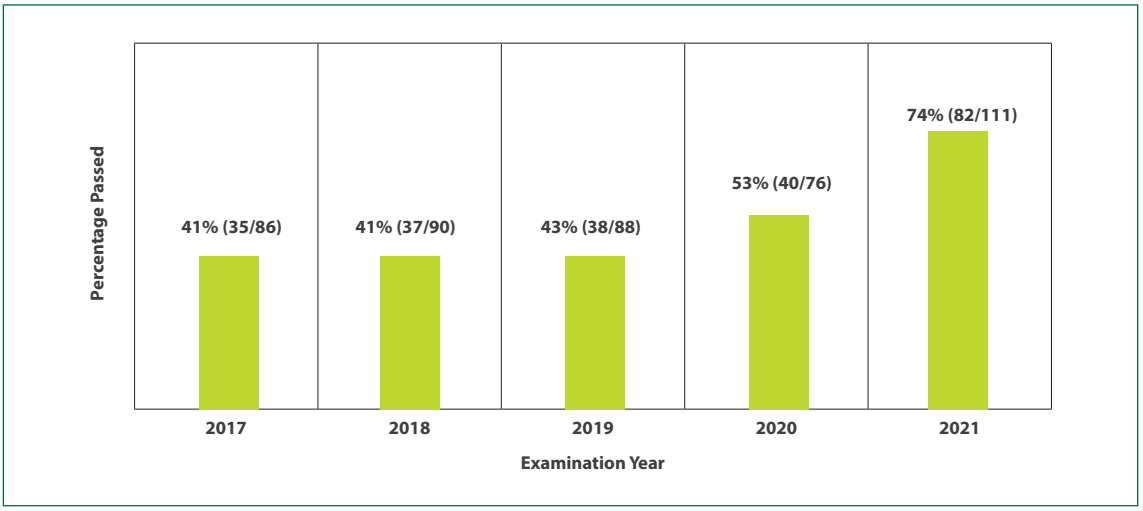

Figure 2: NHLS registrar CMSA exit examinations pass rates trends from 2017 to 2021.

The NHLS also provides a training platform for intern medical scientists, and in the reported financial year, 55 and 15 medical scientists completed in December 2020 and December 2021, respectively (**Table 2**).

Table 2: Number of intern medical scientists who completed training.

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

Project ECHO

NHLS Project Extension for Community Healthcare Outcomes (ECHO) is an innovative remote training solution that creates an expanded and more effective platform for sharing knowledge and developing the skills of professionals in laboratory medicine nationwide.

As indicated in Figures 3 and 4 below, the NHLS Project ECHO has been effectively implemented in 92 hubs, spokes, and mini-hub sites at tertiary (13%), regional (35%), and national central laboratories (29%) in eight provinces. These include expansion to six new sites (1 provincial, 2 district, and 3 regional) between April 2021 and March 2022.

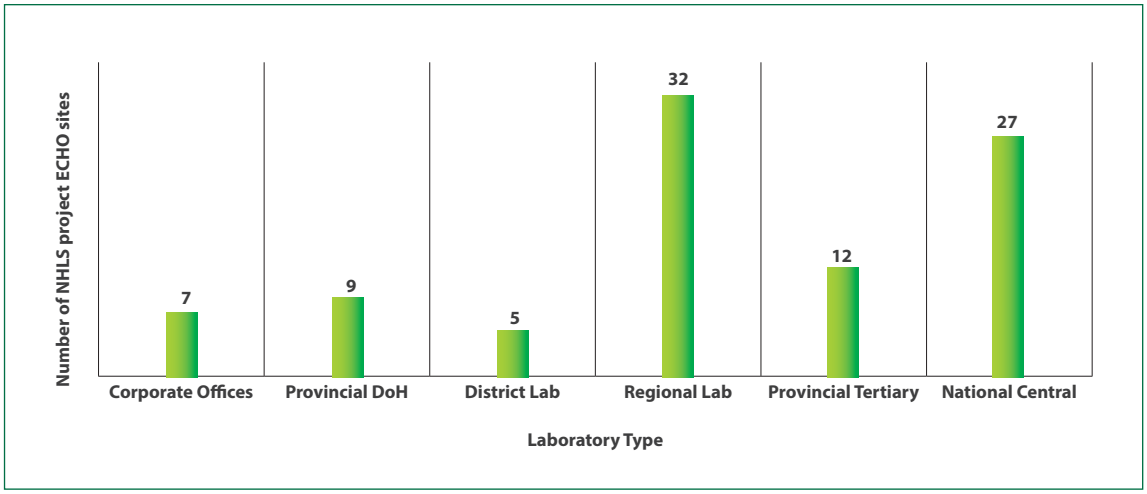

Figure 3: NHLS Project ECHO sites per laboratory type

Figure 4: Project ECHO sessions per province

During the 2021-2022 financial period, 490 Project ECHO sessions were conducted, 49% of which were discipline-specific sessions (242) presented by 211 subject matter experts (Figure 3), whereas 6% were NHLS-specific operational sessions. Individual attendance ranged from 126 to 978 attendees across the discipline-specific and operational sessions. Attendees included registrars, pathologists, professional and intern technicians, technologists and medical scientists, as well as other healthcare workers (Table 3). Multidisciplinary sessions were also conducted, including the NICD Scientific Forum and the Cryptococcal Programme.

Table 3: NHLS Project ECHO Sessions per discipline and attendance (April 2021–March 2022)

Discipline	Number of NHLS Project ECHO Sessions April 2021 to March 2022	NHLS Project ECHO attendees: April 2021 - March 2022							
		Individual Attendees	Registrars	Pathologists	Medical Scientists	Technicians and Technologists	Intern Medical Scientists	Intern Technicians and Technologists	Other
Anatomical Pathology	26	529	103	80	33	230	38	14	31
Chemical Pathology	87	501	88	68	69	178	45	4	49
Research Development and Innovation	11	607	51	49	117	142	101	5	142
Haematology and Immunology	28	847	133	121	74	292	51	8	168
Human Genetics	8	359	28	37	74	80	57	3	80
Microbiology	39	371	87	45	39	37	31	105	27
Multidisciplinary	33	978	61	93	210	303	85	4	222
Operational Sessions	29	340	14	22	24	240	14	-	26
Virology	10	126	29	30	23	10	19	1	14
All Sessions	**271**	**4658**	**594**	**545**	**663**	**1512**	**441**	**144**	**759**

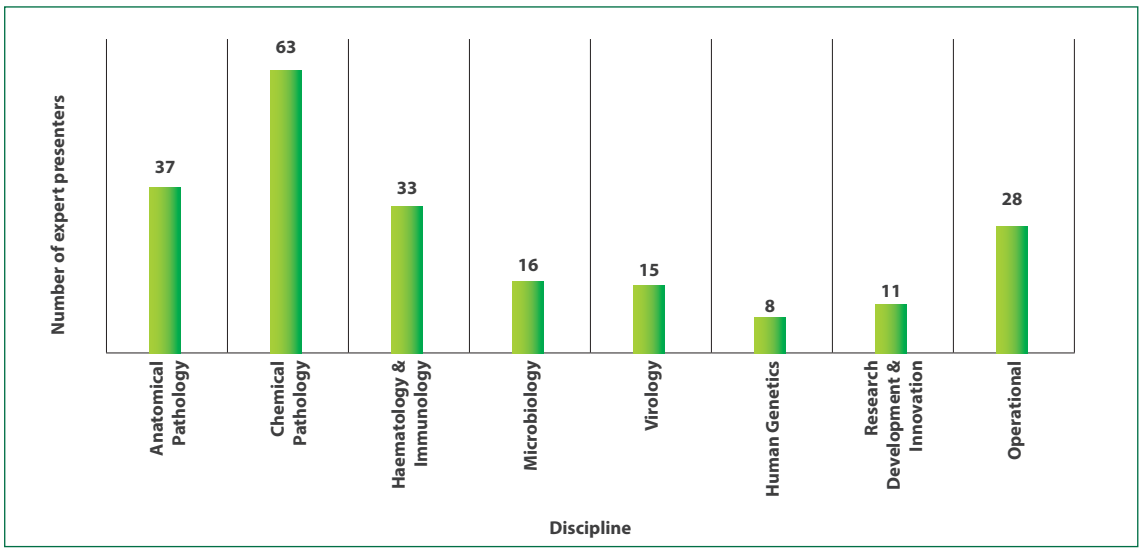

Figure 5: Number of Expert Presenters per discipline

Research support

The NHLS commenced with building capacity for data management and analytics to support NHLS researchers and departments in study design, data collection, and analysis.

Bio-specimen and data access requests for research purposes

In the financial year from 1 April 2021 to 31 March 2022, AAR received 314 material and data access applications via the Academic Affairs and Research Management System (AARMS). Of the submitted applications, 155 (49.4%) were submitted by individuals employed or jointly appointed by the NHLS, while 159 (50.6%) were submitted by applicants not affiliated with the NHLS. The majority of applications (62.4%; n=196) were for data, 10% (n=31) were for samples, while 2.5% (n=8) and 3.5% (n=11) were for permission to use laboratory equipment and conduct scientific surveys, respectively (Figure 6). The remainder of the applications were combinations of two or more of the listed application types.

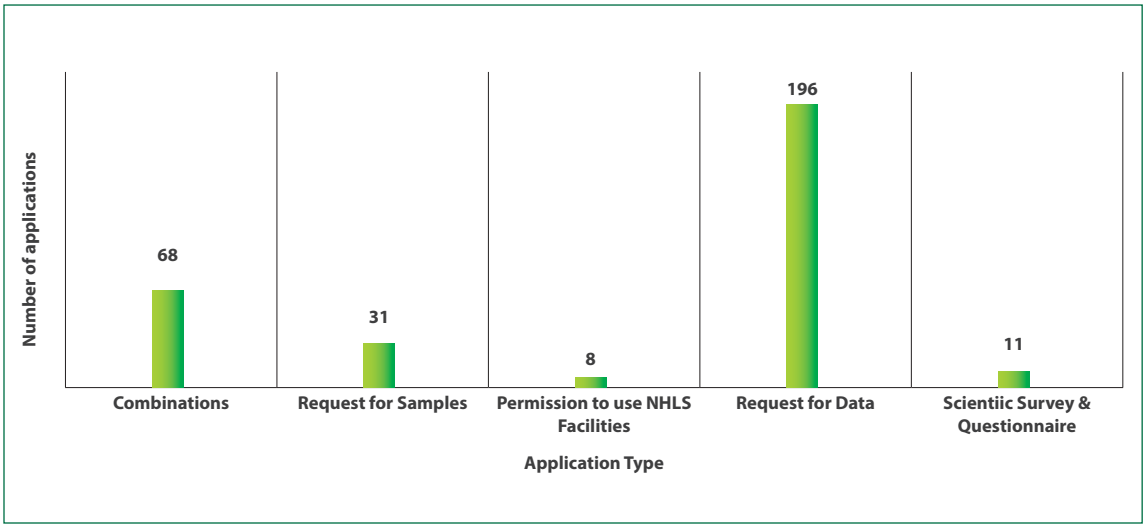

Figure 6: Research requests received by AAR from 1 April 2021 to 31 March 2022

Epidemiology and biostatistics support

Support in epidemiology and biostatistics is provided through consultations, collaborative relationships, and broad-based services in study design, statistical analysis, and data management. In the 2021-2022 financial year, these services were provided to a total of 21 projects or individuals.

The academic affairs and research office has extended the research support initiatives to the UoTs through engagements with various institutional academic and pathology committees.

Training

During the financial year, the AAR office hosted research development lectures and workshops on the ECHO platform. The training sessions were intended for early-career researchers, and the topics covered included the following:

- Framing a research question
- Proposal writing
- Grant writing
- Research study design
- Literature review and meta-analysis
- Secondary data analysis
- Statistics in research
- Research proposal and grant application review processes
- Paving a successful research career

Furthermore, the office hosted special workshops with UoTs and the Gauteng provincial government to guide processes for requesting material and data for research purposes.

PathReD

The Pathology Research Development (PathReD) Congress has grown to become one of the most prestigious and well-attended pathology congresses in South Africa. PathReD mainly creates a platform for the NHLS community to showcase their scientific research, share knowledge, and form and strengthen collaborative networks. Despite being a local congress, the PathReD Congress is organised to meet international standards, ensure scientific integrity, and radiate a culture of academic excellence.

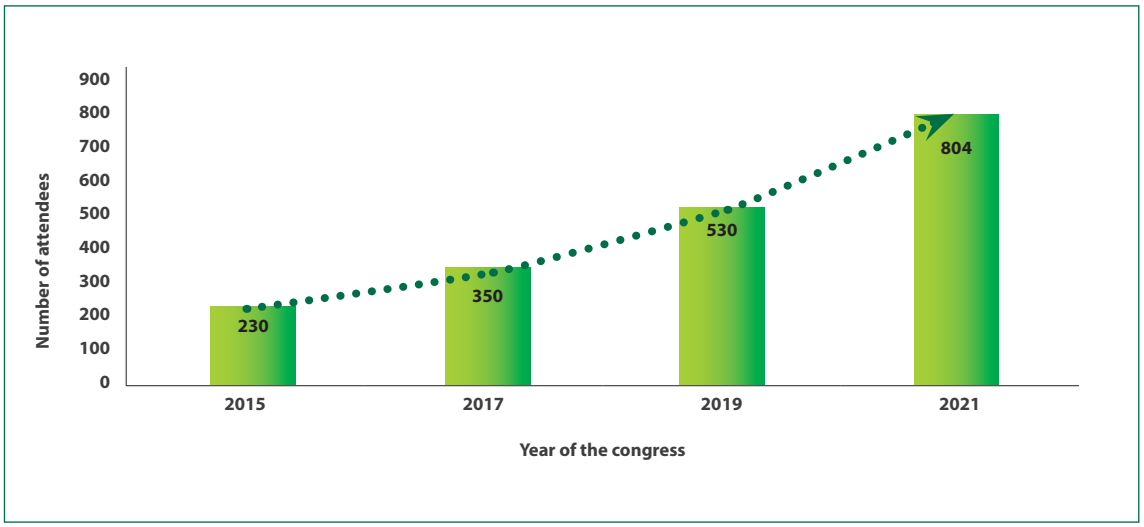

Figure 7: Number of PathReD attendees per congress

The PathReD Congress 2021 was held from the 19th to the 22nd of August 2021 and was the first virtual congress hosted by the NHLS. The 2021 congress attracted 804 delegates, speakers and exhibitors. The observed steep increase in the number of attendees over time serves as a great measure of the recognition of the congress by various stakeholders as well as the need and value of pathology research and training services across the spheres of health.

Scientific Knowledge Centres

The maternal and child health (MCH) scientific knowledge centre (SKCs) committee was the second committee to be established during the financial year. The committee has started with the process of identifying research gaps to craft appropriate interventions. The non-communicable diseases (NCD) SKC committee has proposed six research projects intending to foster collaborations across the NHLS academic centres while addressing knowledge gaps. A collaborative research grant fund has also been recommended by the committee to stimulate cooperation and capacity development in historically- disadvantaged academic centres.

The SKCs will promote innovative research in the key priority areas identified by the NHLS, including TB, HIV, NCDs, MCH, vaccines, the human microbiome, POCT, and health system strengthening. The main objectives of the SKCs are to:

- Identify and address knowledge gaps in the designated key priority areas by performing gap analyses and promoting research and innovation in those identified areas;
- Identify and develop support structures for under-resourced research groups within the designated key priority areas;
- Coordination of research activities in the key priority areas identified;
- Keep stakeholders abreast of new research findings and their implications;
- Strengthen and promote collaboration across all NHLS platforms and improve inter-institutional and multi-sectoral interactions and partnerships;
- Increased funding support for the designated key priority areas; and
- Ensure the rationalisation and best use of financial and human resources.

Grants Finance Management Support

Analysis of project status

The Grants Finance Office (GFO) managed a total of 321 projects during the 2021/22 financial year. Forty new projects were received in the 2021/22 financial year, whereas 281 were carried over from the previous financial year (2020/21). The figure below illustrates the number of managed projects in the past 4 years. There is a decline in the number of projects managed by AARQA. This highlights the urgent need for the NHLS Grants Office to explore new grantors and continuous improvement in the functioning of the office. A lot of effort has gone into establishing grant management processes and providing support to Principal Investigators.

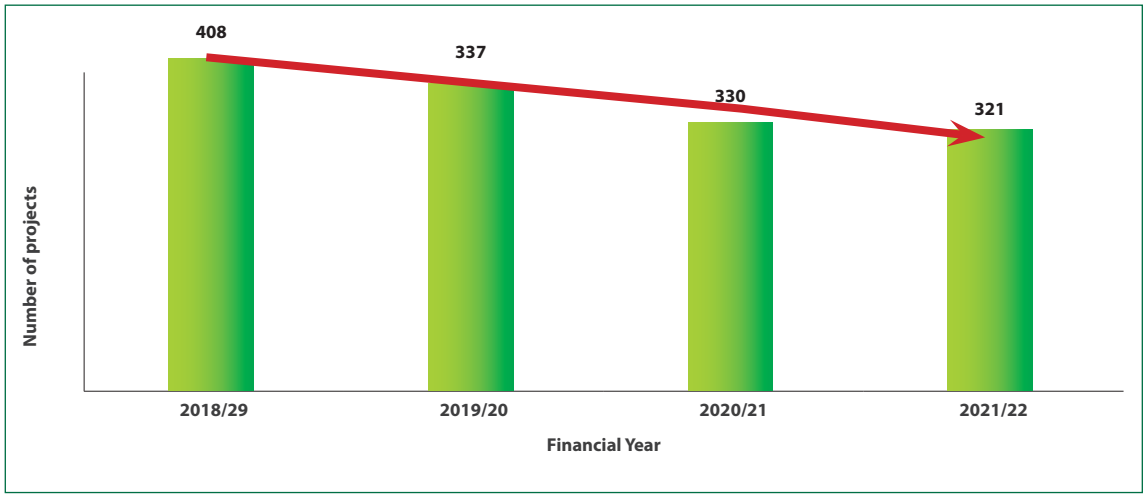

Figure 8: Number of projects managed by the NHLS grants office

Funds available from the top ten grantors as of 31 March 2022

The table below shows that the top ten grantors contribute a total of 91% (R582.3 million) of the total budget of R641.8 million. A total of R185.3 million (29% of the total budget) was spent during the 2021/22 financial year (Table 4). A proportion of 56% (R360 million) of the total budget was new grants received in the 2021/22 financial year (Figure 9).

Table 4: Top Ten Grantors managed by the grants finance office

GRANTORS	Current year budget	Current year expenditure	Commitments	Total expenditure	Avaliable balance	Number of projects	% Spent
Department of Health	297,675,085	46,267,954	4,505,468	50,773,422	246,901,662	4	17%
Centers for Disease Control and Prevention	160,976,400	71,283,625	3,427,626	74,711,251	86,265,149	21	46%
African Field Epidemiology Network	26,303,676	7,008,209	2,872,088	9,880,297	16,423,379	6	38%
Human Sciences Research Council	23,272,939	4,122,668	4,162,181	8,284,849	14,988,090	1	36%
NHLS Research Trust	20,663,801	3,353,690	2,344,448	5,698,138	14,965,663	146	28%
The Biovac Institute	14,555,772	501,787	115,781	617,568	13,938,204	1	4%
World Health Organization	11,541,143	4,820,297	5,313	4,825,610	6,715,533	18	42%
Water Research Commission	11,420,569	6,742,648	324,992	7,067,641	4,352,928	2	62%
Humana People to People in South Africa	10,795,765	-	-	-	10,795,765	1	0%
Elimination eight	8,387,005	771,295	67,417	838,711	7,548,293	2	10%
Other	56,217,493	17,781,838	4,788,781	22,570,619	33,646,874	119	40%
TOTAL	**641,809,648**	**162,654,011**	**22,614,096**	**185,268,106**	**456,541,541**	**321**	**29%**

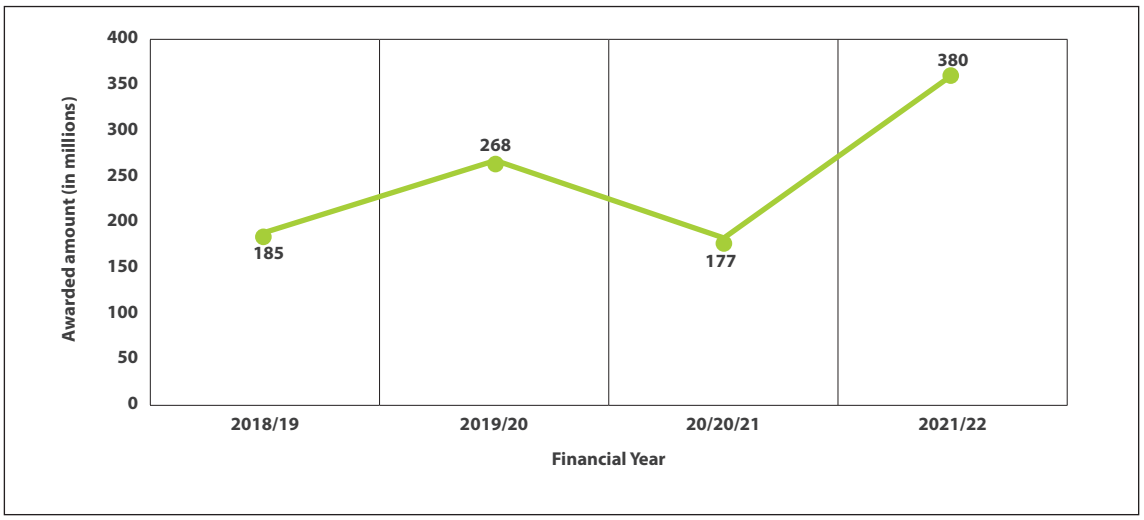

Figure 9: New funding amounts received by the NHLS grants office in the past four financial years.

Research funding

NHLS Research Trust

A total of 60 applications were received during financial year 2021/22. Eight (13%) were for the research grant with a maximum award of R500 000, two (3%) were for the Research Progression Grant with a maximum award amount of R250 000, and 50 (84%) were for the development grant with a maximum award amount of R100 000.

The status of the applications is reflected in the table below.

Table 5: NHLS Research Trust Applications Update

Application status	2021				2022				2021/22
	Development	Research Progression	Research	All	Development	Research Progression	Research	All	Total
	R100 000	R250 000	R500 000		R100 000	R250 000	R500 000		
Awarded	4		2	**6**				**0**	**6**
Cost Centre Opened	22		6	**28**				**0**	**28**
Rejected	12	1		**13**		1		**1**	**14**
Sent for Peer Review				**0**	3			**3**	**3**
Reviewed - Pending NHLSRT Input	4			**4**	5			**5**	**9**
All Applications	**42**	**1**	**8**	**51**	**8**	**1**	**0**	**9**	**60**

Kick-Start Project Funding

Kick-Start Project Funding (K-Project Funding) is a research grant funding opportunity provided by the NHLS to stimulate research by NHLS staff who are commencing their research activities and who are not yet eligible for funds from other sources. K-Projects Funding was created to provide young researchers with the opportunity to attract competitive grants to kick-start their research careers. The ethos of K-Project Funding is to encourage and support developmental research for emerging researchers, including Registrars, emerging medical scientists, and other NHLS staff conducting research.

The table below provides a summary of the K-Project funding applications and the status for the 2021 – 2022 financial year.

Table 6: Kick-Start Project (2021-2022)

CATEGORY	2021	2022	GRAND TOTAL
Awarded	2	1	3
Cost Centre opened	17		17
Executive review		1	1
Rejected	1		1
Sent for peer review		1	1
GRAND TOTAL	**20**	**3**	**23**

Research outputs

Publications

A total of 688 journal articles that were co-authored by NHLS researchers were published in indexed journals during the financial year. Information on authorship by the university is indicated below.

Table 7: Number of publications co-authored by NHLS researchers per institution

Institution	Apr 2021 - Mar 2022		
	No of publications	First author	Last author
Sefako Makgatho University	12	6	1
University of the Witwatersrand	218	113	71
University of Cape Town	121	64	18
University of Limpopo	2	0	1
University of Pretoria	64	35	13
Stellenbosch University	76	41	21
University of Free State	42	12	8
University of KwaZulu-Natal	55	28	11
University of the Western Cape	6	1	0
Walter Sisulu University	5	0	1
NHLS only	87	29	21
TOTAL	**688**	**329**	**166**

NHLS Intellectual Property

The Intellectual Property (IP) Policy was approved and implemented during the 2021/2022 financial year. The policy aims to govern the rights that accrue among the NHLS, universities, and other stakeholders in relation to fostering collaborative inventions, discoveries, and improvements and to facilitate the effective identification, protection, utilisation and commercialisation of NHLS IP for the benefit of the South African public as required by the Intellectual Property Rights Act.

Quality Assurance

Accreditation and Certification

During this reporting period, the NHLS continued to implement and improve the QMS in laboratories and departments against different international standards, namely, the International Organisation for Standards (ISO) / International Electrotechnical Committee (IEC) 9001:2015, ISO 15189:2012, ISO/IEC 17020:2012, ISO/IEC 17025:2017 and ISO/IEC 17043:2010.

The Quality Assurance Unit, through the Q Pulse office, continued to support the implementation and maintenance of the QMS by ensuring that the policies and procedures were controlled in compliance with the required standards. The team ensured that NHLS staff are equipped with the right skills to manage different modules of the QMS software by training 540 staff on different Q Pulse modules compared to five in the 2020/21 financial year. The number of active documents on the system increased from 8398 at the end of the financial year 2021 to 8 500 at the end of the financial year 2022 due to an increase in accreditation and certification.

The accreditation and certification process is as follows: Auditors or assessors are sent by the relevant external body to the NHLS to review the QMS. At the end of their visit, they make a recommendation based on their assessment. They then send the documents to the accreditation or certification body to finalise the process. The documents are then reviewed following the body's processes. Following that, a certificate is issued and sent to the NHLS. The time between the visit and the issuing of the certificate varies between two and six months.

ISO 15189:2012 accreditation of medical laboratories

The total number of accredited diagnostic laboratories increased as the SANAS conducted initial assessments in 18 laboratories compared to 15 in the previous financial year. This passed a 100 (109) milestone of accredited NHLS laboratories even though, by 31 March 2022, the majority of them (10) had not yet received certificates for various reasons, including the SANAS backlog. At the end of March 2022, the total number of laboratories with certificates was 99/216 (46%). The figure below shows the accredited laboratories distributed across all nine provinces in 45/52 (87%) metropolitan and district municipalities. Over five years ago, 22/99 (22%) of these laboratories were enrolled in the US President's Emergency Plan for AIDS Relief (PEPFAR)-funded Strengthening Laboratory Management Toward Accreditation (SLMTA) quality improvement initiative.

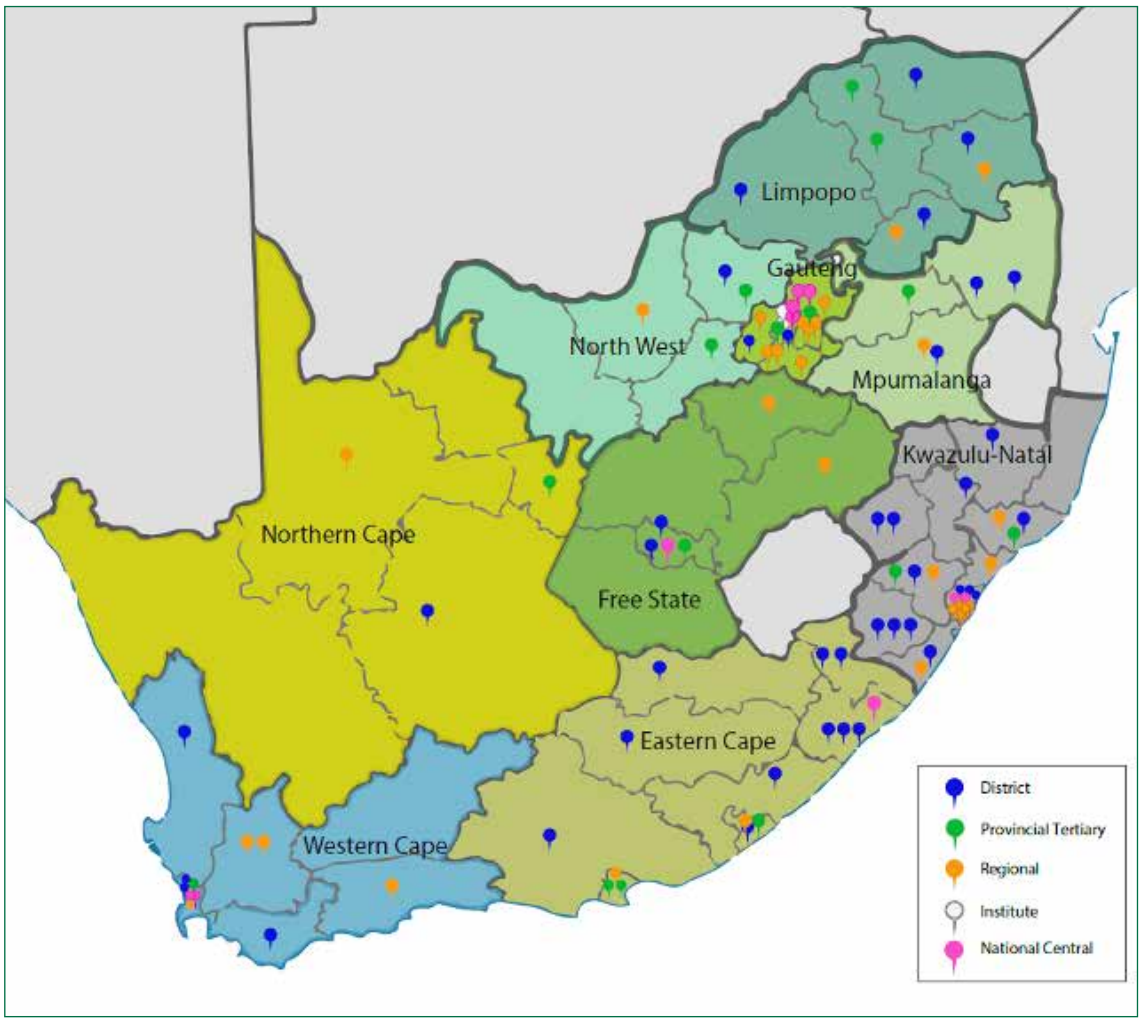

Figure 10: Accredited diagnostic laboratories with certificates by 31 March 2022

Figure 11 below shows the NHLS accreditation journey from 2000 to 31 March 2022 per various laboratory tiers. Most of these laboratories are district laboratories (42/99 42%) that were included in the accreditation plan later in the years. All four tiers of laboratories achieved the Annual Performance Plan (APP) target, with Regional and District laboratories exceeding the targets by two and 14 laboratories, respectively.

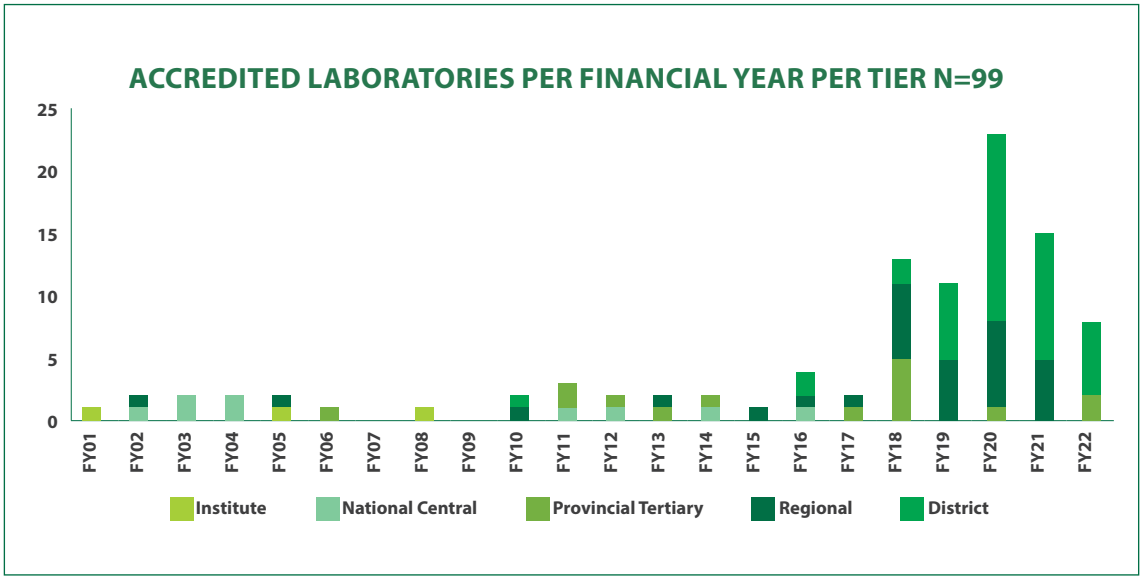

Figure 11: Accredited laboratories with certificates by 31 March 2022 per tier and financial year

ISO/IEC 17020:2012 accreditation of occupational hygiene laboratories

The Occupational Hygiene section of the NIOH is the only part of the NHLS complying with this standard. They maintained the accreditation during the current financial year (100%).

ISO 17025:2017 accreditation of public health laboratories

The number of accredited laboratories against this standard remained the same as 3/5 (60%) laboratories (NICD, NIOH, and Public Health) that maintained their accreditation, and no new laboratory was accredited during the financial year 2022.

ISO/IEC 17043:2010 accreditation of Proficiency Testing Schemes (PTS)

There was an increase in the number of accredited PTS from 26 in the 2020/21 financial year to 28 in the 2021/22 financial year. In addition, Chemistry and Endocrine had scope extensions to their accreditation. The newly accredited PTS and extensions are as follows:

- Automated differential count
- Mycobacteriology (MTB) LPA
- Chemistry – extended the accredited analytes by Transferrin
- Endocrine – extended the accredited hormones by Ferritin

The vast majority, 85% (28/33) of the schemes, are accredited. The table below shows the accredited PTS by discipline and percentage accredited.

Table 8: NHLS accredited PTS by 31 March 2022

NO.	DISCIPLINE	PTS NAME
11.	Chemical Pathology (7/7) 100%	• Blood gas • Beta hCG (Pregnancy Test) • Cardiac Markers • Chemistry – general • C-Reactive Protein • Endocrines • Therapeutic Drug Monitoring
2.	Haematology (8/9) 89%	• Automated Differential Count • Blood Morphology • Differential count – manual • D-Dimer • Erythrocyte sedimentation rate • Flow cytometry (including CD4) • Full (complete) blood count
3.	Microbiology (11/12) 92%	• Bacteriology • Cryptococcus latex antigen • MTB LPA • MTB Microscopy • Mycology Moulds • Mycology Yeast • Non - Treponemal syphilis • Parasitology – Blood • Parasitology - Malaria Rapid Diagnostic Test • Parasitology – Stool • Specific Treponemal syphilis
4.	Virology (3/6) 50%	• Hepatitis B Surface Antigen • Human Immunodeficiency Virus (HIV) Serology • HIV Early Infant Diagnosis

ISO 9001:2015 certification of support service departments and Diagnostic Media Products (DMP)

The number of certified departments increased from three to four, with the QAD unit of AARQA joining DMP-Greenpoint, DMP–Sandringham, and NIOH Biobank through successful Stage one and Stage two external audits during the 2021/22 financial year.

To continue improving the QMS in support service departments, training was conducted through virtual platforms covering six topics in 12 sessions during the COVID-19 pandemic. The number of staff trained increased to 384, addressing six topics, compared to 349 in the previous financial year, addressing the same number of topics.

The figure below shows compliance with the ISO 9001:2015 standard requirements, as determined through internal audits. Clauses have shown year-to-year improvement increased to 5/7 (71%) in the 2021/22 financial year compared to 2/7 (28%) in the 2020/21 financial year.

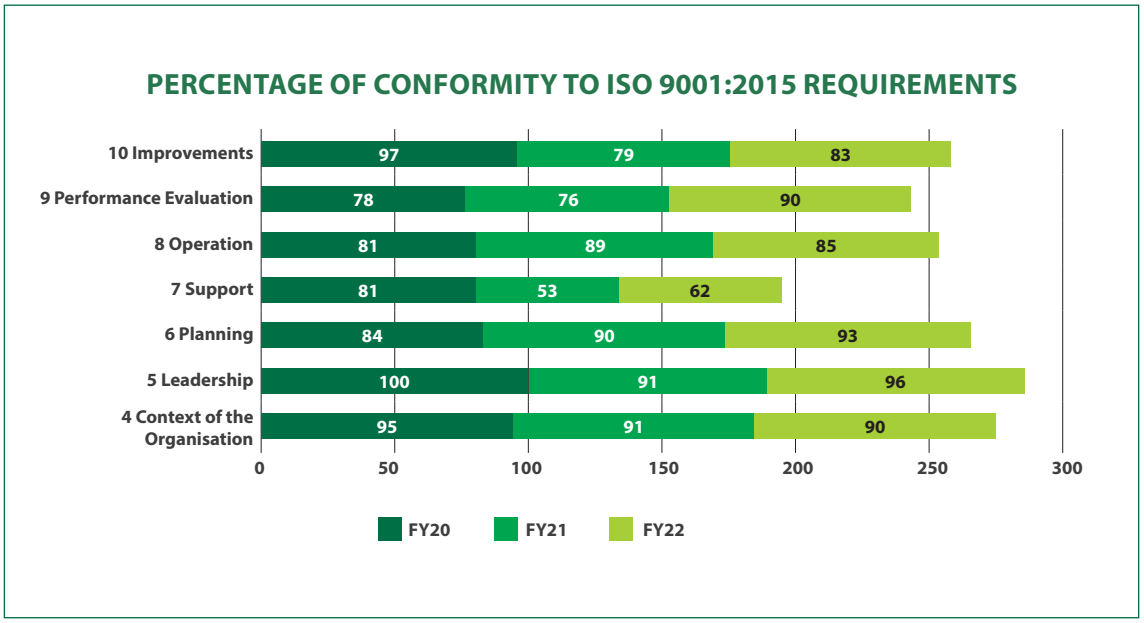

Figure 12: Percentage compliance of support service departments in three audit cycles

Proficiency Testing Schemes

QAD continued to provide the PTS to all NHLS laboratories and private laboratories in South Africa, as well as public and private laboratories in other countries. The figure below shows the 16 African countries participating in the NHLS PTS during the 2021/22 financial year. The 17th country participating is the United States of America. The number of participating countries remained the same in the two financial years even though Liberia did not enroll in the 2021/22 financial year. Liberia was replaced by Angola, although Angola was not enrolled in the previous financial year.

Figure 13: Countries enrolled in the NHLS PTS during the 2021/22 financial year

In addition to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) molecular PTS introduced in the 2020/21 financial year, the SARS-CoV-2 antigen PTS was introduced during the 2021/22 financial year following quick and successful pilot studies. These schemes did not follow the typical process of being offered in NHLS laboratories but rather the pilot due to demands in other countries.

The number of enrolments increased from 8383 in the 2020/21 financial year to 9009 in the 2021/22 financial year. The increase is mainly due to the SARS-CoV-2 schemes, as both have 202 enrolments.

The NHLS laboratories continue to issue good quality results, and this is supported by the observed performance.

The figure below shows that 96% of reporting laboratories achieved average results of more than 80% on 33 PTS. They continue to exceed the APP target of 90% over five consecutive years.

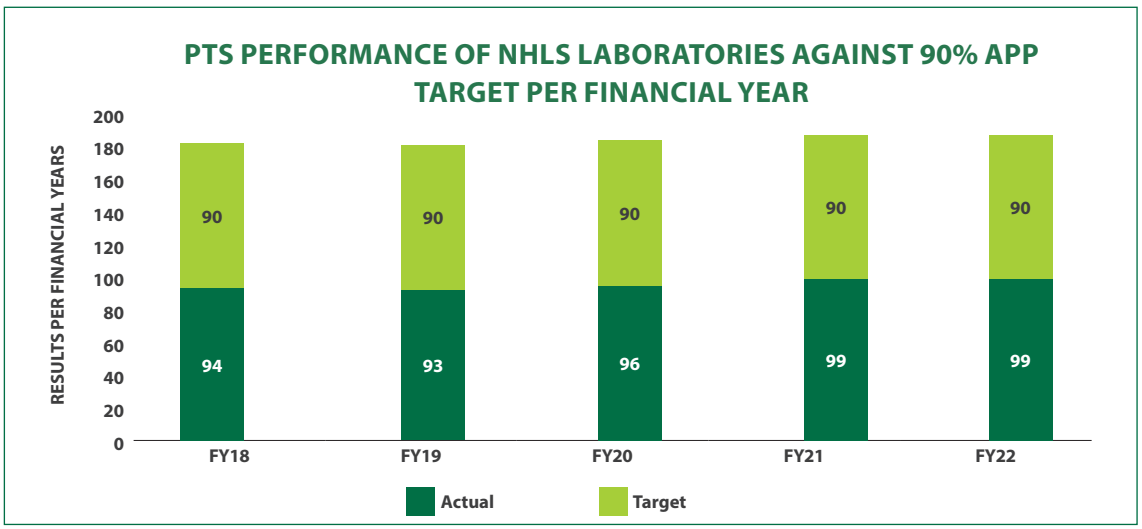

Figure 14: Average PTS performance of NHLS laboratories over five years

In addition to SLMTA, PEPFAR continued to fund HIV PTS for all POCT sites in the country. The number of enrolments increased from 4125 in the 2020/21 financial year to 4237 in the 2021/22 financial year. The overall performance of the POCT sites increased from 85% in the 2020/21 financial year to 98% in the 2021/22 financial year. Figure 15 below shows the number of facilities participating and the average performance as a percentage on the PTS per province in brackets, with the the 2020/21 financial year results in lime green and the 2021/22 financial year results in forest green.

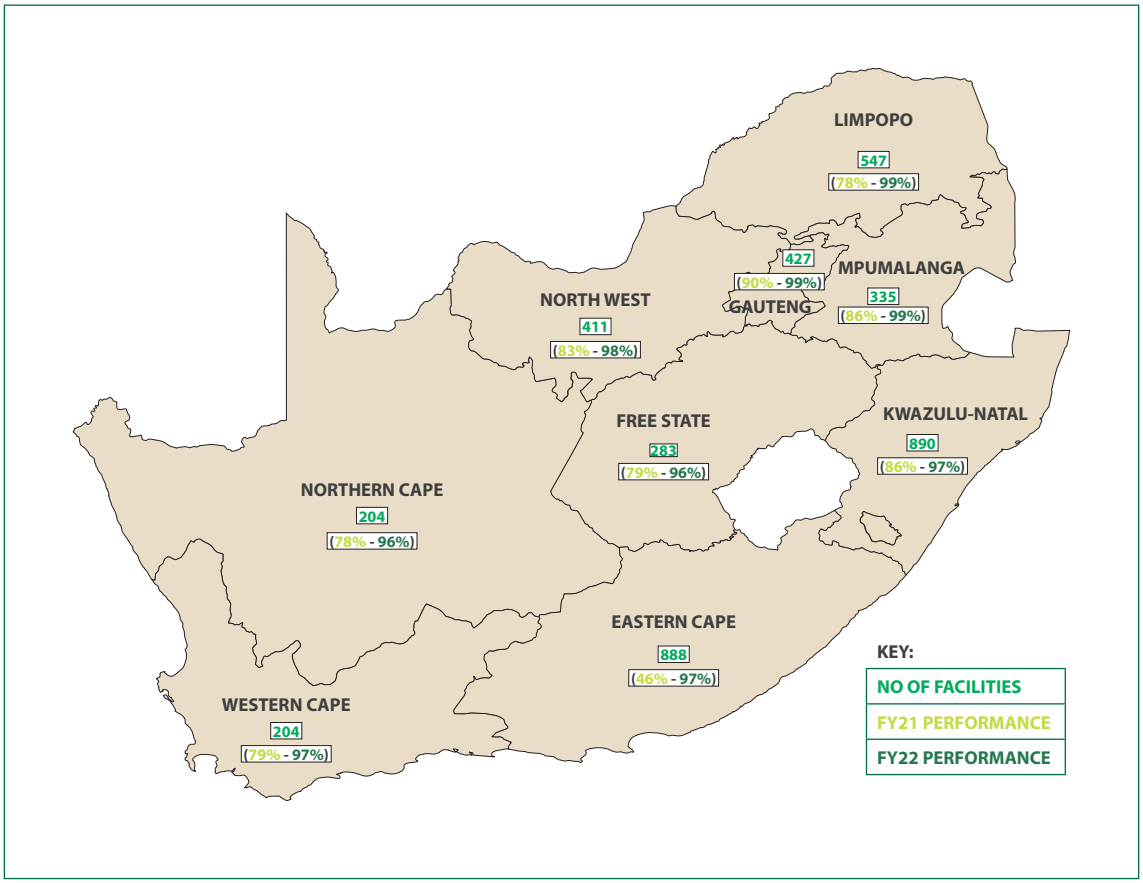

Figure 15: PTS performance of POCTs over two financial years and number of facilities

Quality Compliance Audits (QCA)

As more laboratories become accredited, the number of laboratories undergoing QCAs decreases. During the 2021/22 financial year, only 123 laboratories went through this audit. The QMS in non-accredited laboratories continues to show improvement, as the performance of laboratories achieving an average of 80% or more increased by 5% (from 93% in the 2020/21 financial year to 98% in the 2021/22). Figure 16 below shows the QCA performance of the NHLS laboratories compared to the APP targets over the last four years.

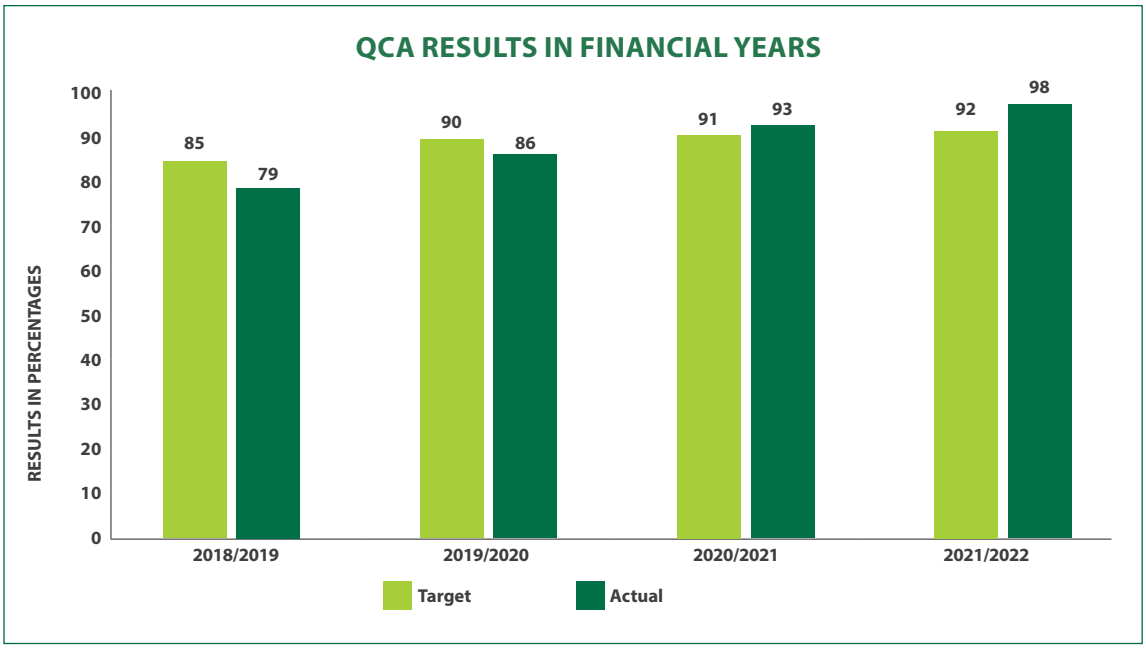

Figure 16: NHLS QCA results over four financial years

Health Technology Assessment and Post-Market Surveillance

The QAD Health Technology Assessment (HTA) unit continued to ensure that the NHLS laboratories use in-vitro devices (IVDs) (equipment, kits, reagents, etc.) that are of good quality by conducting thorough evaluations. The majority of the evaluations are initiated to comply with the requirements of both the NHLS HTA for procurement purposes and the SAHPRA. Staff continues to assist SAHPRA in capacity building in various ways, including reviewing dossiers and providing technical support.

The team continues to improve its processes and engage stakeholders through quarterly meetings with the representation of the South African Laboratory Diagnosis Association (SALDA), weekly individual supplier meetings and various NHLS discipline-specific Expect Committee meetings. There was an increase in the number of HTA requests received from 32 in the 2020/21 financial year to 44 in the 2021/22 financial year. The requests are from both SALDA and non-SALDA members, as well as NHLS staff initiation. The number of closed projects also increased from 31 in the 2020/21 financial year to 36 in the 2021/22 financial year, with fewer projects active (from 34 at the end of the 2020/21 financial year to 25 by the end of the 2021/22 financial year). Figure 17 on page 104 shows the activities related to HTA for the last three financial years.

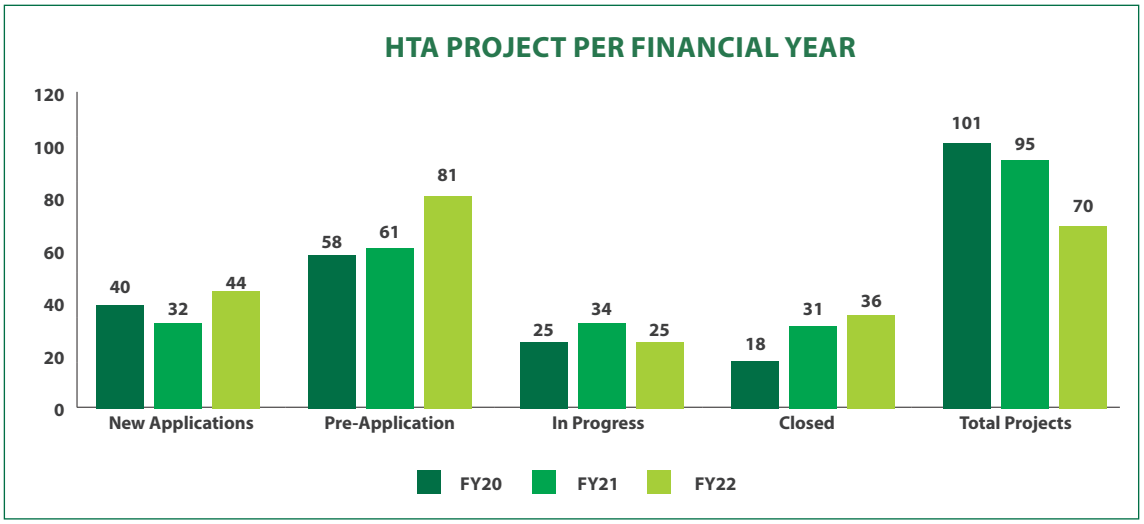

Figure 17: Summary of HTA activities over three years

The Post-Market Surveillance (PMS) Unit continued to ensure that the IVDs produced and placed in laboratories continue to meet the desired quality, safety, and performance requirements. The number of PMS incidents was 19 in the reporting period, compared to eleven in the previous financial year. The majority, 14/19 (74%), were contractual, while the remaining 5/19 (26%) were technical. All PMS incidents were fully addressed and closed. The figure below shows the number and category of PMS incidents over three financial years.

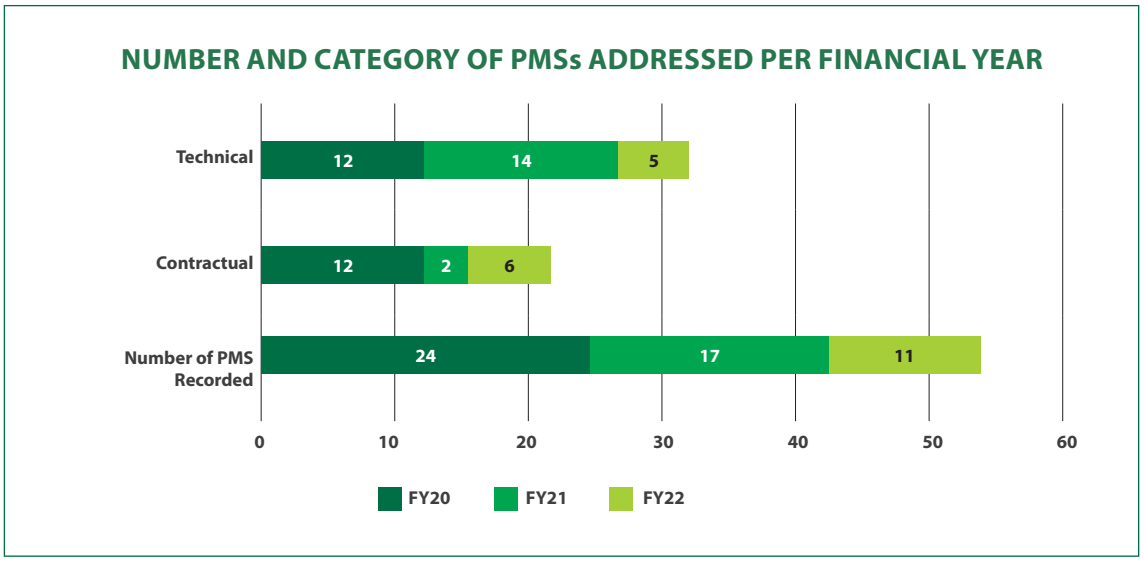

Figure 18: PMS activities over three financial years

PERFORMANCE INFORMATION BY INSTITUTES

NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES

Prof Adrian Puren
Executive Director

Introduction

The essential services provided by the NICD continues to be underpinned by the protracted COVID-19 pandemic, in addition to other communicable disease concerns that affect the South African population, the Southern African Development Community (SADC) region and Africa. These strategic services include disease surveillance, specialised diagnostic services, outbreak response, research and training, and provincial epidemiology capacity building.

The institute plays a central role in detecting, containing and responding to infectious disease threats, and provides extensive technical support and expertise to the NDoH, the WHO and the Africa CDC. As a credible health partner, the institute furthermore provides the global health community with valuable information on communicable diseases.

The NICD comprises seven disease-focused centres and the staff complement includes pathologists, scientists, epidemiologists, medical technologists and technicians, and surveillance officers.

Centre for Emerging Zoonotic and Parasitic Diseases (CEZPD)

The Centre for Emerging Zoonotic and Parasitic Diseases (CEZPD) is a national and regional hub for diagnosis, surveillance, outbreak response, research, teaching and training related to zoonotic viral, bacterial and parasitic diseases, particularly those associated with risk groups three and four pathogens. These includeviral hemorrhagic fevers (VHFs) such as Ebola and Marburg viral diseases, Lassa fever and Lujo hemorrhagic fever (LHF); arthropod-borne diseases such as Rift Valley fever (RVF), Crimean-Congo haemorrhagic fever (CCHF), yellow fever, dengue fever, chikungunya fever, Sindbis fever, West Nile fever, Zika fever, malaria, plague and rickettsioses; rabies and rabies-related infections; bacterial diseases such as anthrax, botulism, brucellosis and leptospirosis; parasitic opportunistic infections; diarrhoeal disease in children under five years of age; Schistosomiasis and soil-transmitted helminthic diseases. The centre operates highly specialised laboratory facilities, including the positive-pressure suit biosafety level (BSL) 4 and 3 laboratories, a transmission electron microscope laboratory and insectaries for housing the vectors of malaria and arboviruses for insecticide resistance and vector competence studies. These facilities constitute an essential resource capacity for diagnosis, surveillance, outbreak response and research of priority zoonotic viral, bacterial and parasitic diseases in Africa.

The Special Viral Pathogens Laboratory (SVPL) has conducted passive laboratory-based surveillance for human rabies in South Africa since 1981. In 2021, a significant increase in dog rabies was noted in eThekwini, KwaZulu-Natal, and in Buffalo City and Nelson Mandela Bay in the Eastern Cape province. The resurgence of dog rabies in these provinces is considerable, and a high number of dog rabies cases will continue to be reported through the first quarter of 2022. The ongoing epizootics of dog rabies have also led to an increase in reported human rabies cases. A total of 17 human rabies cases were laboratory-confirmed from 1 April 2021 to 31 March 2022 in these two provinces.

The SVPL also conducts laboratory investigations of VHFs in South Africa. The laboratory provides laboratory testing for both endemic VHFs (such as Crimean-Hemorrhagic fever, CCHF and RVF) and non-endemic VHFs (such as Ebola,Marburg virus disease and Lassa fever). In 2021, a single case of CCHF was confirmed from the Western Cape province and another case from the same province in Feb 2022. Historically CCHF cases have been reported from all nine provinces of South Africa with the most significant cases having been recorded from the Free State, Northern Cape and North West provinces. VHF is a Category I notifiable medical condition in South Africa. The first imported case of hantavirus infection in South Africa was also confirmed in 2021. The latter involved a South African businessman with a travel and exposure history in Croatia. He was diagnosed and managed in South Africa.

To alert public health authorities to the possibility of increased human plague risk, the CEZPD Special Bacterial Pathogens Laboratory (SBPL) continued surveillance for plague in susceptible rodent populations in Nelson Mandela Bay Municipality (Coega area) and eThekwini Municipality. None of the rodents tested positive for plague anti-F1 antibodies.

The Arbovirus Reference Laboratory (ARL) investigated endemic and exotic arboviral disease cases, including chikungunya, RVF, dengue, Zika, Ross River and Japanese encephalitis. The laboratory experienced a slight increase (~20%) in diagnostic submissions since the gradual return of the health care system and travelling due to COVID-19 restrictions (from 71 recommendations in the previous year to 90 during the period under review).

Centre for Enteric Diseases (CED)

The areas of focus for CED include foodborne and waterborne diseases; priority enteric diseases under routine surveillance thatcomprise epidemic-prone conditions, for instance enteric fever, cholera and listeriosis; rotavirus that is a vaccine-preventable disease in South Africa; diarrhoeal disease syndromic surveillance; and genomic surveillance of priority enteric bacterial pathogens.

Diarrhoeal diseases sentinel surveillance is active at five sites in three provinces. No less than383 cases were enrolled with 229 from Western Cape, 116 from North West and 37 from Free State). Children ≤5 years constituted 90% of cases (343/383) with an average age of 14-months. The testing of diarrhoeal specimens remain ongoing and no rotavirus has been detected in 2022 at the time of publishing.

Seventy-two cases of listeriosis were reported from seven provinces with the majority of cases from Western Cape (36%, 26/72), Gauteng (31%, 22/72) and KwaZulu-Natal (19%, 14/72). An average of one case per week (range: 0-4 cases per week) was recorded. The majority of the cases are newborn babies ≤28 days (33%, 24/72), followed by persons in the following age groups: 15-49 years (31%, 22/72), ≥65 years (22%, 16/72), 50-64 years (13%, 9/72), and lastly children between 30 days and 14 years (1%, 1/72). No cases were reported from Northern Cape and North West.

By using whole-genome sequencing (WGS) analysis, clusters (small localised outbreaks) were identified in Western Cape and North West. In Western Cape three clusters were identified in three different districts, and in North West there was a cluster in the Dr Kenneth Kaunda District. The first cases in all clusters occurred in 2020. As of 31 March 2022, the City of Cape Town cluster and the Garden Route cluster comprised 18 and 15 cases, respectively. The last case of the Winelands cluster strain was identified in May 2021. The Klerksdorp cluster strain was also identified in other provinces with cases totalling 35 across five provinces [North West (21), Gauteng (6), Mpumalanga (4), KwaZulu-Natal (2) and Free State (2)]. Most (43%; 15/35) of the cases are males of working-age group (15 – 49 years). Outbreak investigations are ongoing for all clusters and no definite source(s) of infection have been identified for the Western Cape clusters. In-depth interviews of 26/35 Klerksdorp cluster cases showed an association with the consumption of contaminated water in gold mines located in the district. Due to the demographics of the cases and the scale, contamination of municipal water is extremely unlikely to be the source of infection in any of these clusters.

Gauteng reported higher than usual numbers of enteric fever cases between January and March 2022. A new cluster was identified in Gauteng, comprising of 20-cases that were diagnosed from January 2020 to February 2022. The cases were not restricted to a single district and span a range of age groups. CED continued to provide technical advice and support to the provincial and district health departments with outbreak investigations, and local communities were supported through education and information on enteric fever.

All alerts of suspected outbreaks reported through the NMC system were investigated with the necessesary epidemiological and laboratory support being provided. During the reporting period, CED responded to 10 outbreaks. An additional 55 suspected foodborne disease outbreaks were reported, but insufficient epidemiological data and the absence of appropriate specimen collection precluded further investigation.

Centre for Healthcare-Associated Infections, Antimicrobial Resistance and Mycoses (CHARM)

The centre incorporates two national reference laboratories for antimicrobial resistance (AMR) and mycoses, accredited to ISO 15189: 2012 requirements, and houses the National Stock Culture Collection of pathogenic bacteria and fungi. The centre continues to function as a WHO Collaborating Centre for AMR, and is the national focal point for WHO's Global AMR Surveillance System (GLASS). The centre's epidemiology team supports priority surveillance projects, conducts outbreak investigations and is involved in the set-up and evaluation of public health programmes.

The centre implemented a real-time alert system to detect outbreaks of healthcare-associated bloodstream infections among newborn babies. Improvements to the application were completed, and the surveillance was re-launched at Dora Nginza hospital (Eastern Cape) in 2022. Feedback received through informal consultations at this site highlighted some additional development needs to enhance the application. A formal evaluation of the surveillance system will be conducted in 2022, before further work on the application is undertaken.

Members of the centre represented the NICD on a newly constituted Ministerial Advisory Committee for AMR, the WHO AMR Surveillance and Quality Assessment Collaborating Centres Network, the WHO Strategic and Technical Advisory Group for AMR, and the WHO Fungal Pathogens Priority List Advisory Group. The centre for AMR surveillance currently uses several approaches. These include the following:

National or sentinel isolate-based surveys: Bacterial and fungal isolates, cultured from patients who meet the surveillance case definitions, were submitted to the centre's reference laboratories for identification, antimicrobial susceptibility testing and genotyping. During the period under review, the centre conducted surveillance for bacteraemia caused by carbapenem-resistant Enterobacterales (2015-2021), enterococci, and all infections caused by Candida auris (2018-2021).

Enhanced laboratory surveillance: Detailed clinical information was collected from patients admitted to sentinel hospitals who met the surveillance case definitions. During the period under review, this was suspended. More recently, electronic laboratory surveillance revealed that annual data compiled on bloodstream infections caused by the ESKAPE bacterial pathogens and Candida. The NICD merged line list data from the public and private-sector pathology laboratory information systems, cleaned the data and made it available through the AMR dashboard on the NICD website. The dashboard displays interactive and exportable AMR maps by geographic location, pathogen, antimicrobial agent and health sector. AMR data for the public sector are available at the facility level, and aA combined public and private AMR report on key organisms and antimicrobial agents is available from the NDoH (http://www.health.gov.za/index.php/antimicrobial-resistance).

Since 2018, the WHO has recommended a combination of amphotericin B and flucytosine (5-FC) as a first-line induction treatment for cryptococcal meningitis. In December 2021, 5-FC was registered by the South African Health Products Regulatory Authority (SAHPRA). Approximately 80-hospitals participated in a 5-FC access programme, and the centre continued to assist with the coordination of data collection and analysis. A manuscript on the outcomes of 5-FC-containing combination treatment for cryptococcal meningitis was accepted in The Lancet Infectious Diseases. A member of the centre co-chaired the WHO Guideline Development Group on Cryptococcal Disease in 2022 and

the WHO updated its recommendation for first-line treatment of cryptococcal meningitis. Passive laboratory-based surveillance for rarer invasive mycoses continued.

The centre led or participated in the investigations of several healthcare-associated outbreaks during the period under review. The centre's contribution to outbreaks has shifted from epidemiological assistance to molecular studies. This may signal changing priorities prompted by the COVID-19 pandemic to investigate and manage healthcare-associated outbreaks.

As a WHO Collaborating Centre for AMR, CHARMparticipated in the WHO AMR Surveillance and Quality Assessment Collaborating Centres Network, which was formed to support the implementation of GLASS (https://www.who.int/glass/reports/en/). The NICD collaborated on activities to strengthen countries' capacity for developing and implementing AMR surveillance programmes and provided an external quality assessment programme (https://ptschemes.nicd.ac.za/Home/Bacteriology).

Centre for HIV and STIs (CHIVSTI)

The HIV and SARS-CoV-2 Virology Section were involved with COVID-19 related research, focusing on characterisation of immune responses to variants of concern in various epidemiological cohorts and COVID-19 clinical trial vaccines. The data provided insights that informed likely responses in cases of natural infections, including previous infections and variants and responses in vaccines. Through the Global Immunology and Immune Sequencing for Epidemic Response (GIISER) and the Coronavirus Immunotherapy Consortium CoVICIS projects, the laboratory has been involved in establishing capacity development through new assays and sharing reagents within the networks that form part of these collaborative programmes. Collaborations have also been established with pre-clinical developers of novel vaccines, including the WHO-sponsored South African mRNA Vaccine Consortium (SAMVAC) and Greenlight Biosciences. The SARS-CoV-2 ELISA assay developed in the laboratory passed SANAS accreditation in February 2022. In addition, the centre continued to pursue studies of the ontogeny of broadly neutralising antibodies in HIV infection, to inform vaccine design. There are ongoing adult HIV cure studies, including conducting immunological and genetic analyses of studies.

HIV and STI surveillance, and monitoring and evaluation of HIV antiretroviral treatment programmes were critical activities. The centre supported Operation Phuthuma, a NDoH programme aimed at improving the quality of healthcare management at the facility level. The NICD provided routine HIV laboratory reports for the Results for Action Reporting and supported validation of facility DHIS data and validation in meeting the UNAIDS targets for the numbers of persons with HIV knowing their status, the numbers of persons with HIV on treatment and the virally suppressed. The association between viral suppression during the third trimester of pregnancy and unintended pregnancy among women on antiretroviral therapy: results from the 2019 Antenatal HIV Sentinel Survey, South Africa showed an association between unsuppressed viral load and unintended pregnancy among pregnant women who initiated ART before pregnancy. The study highlighted the need to strengthen the routine assessment of fertility preferences and provision of contraceptive services for HIV positive women receiving antiretroviral therapy.

Case surveillance of congenital syphilis continued together with STI Sentinel Aetiological Surveillance at three primary healthcare centres: Alexandra Health Centre (Gauteng); Prince Cyril Zulu Communicable Diseases Centre (KwaZulu-Natal), and Spencer Road clinic (Western Cape). In addition, a new surveillance site was established for MSM surveillance at a sentinel Men's Health Centre in central Johannesburg. The surveillance aims to develop early warning for evolving resistance to extended-spectrum cephalosporins in Neisseria gonorrhoeae and emerging STIs such as lymphogranuloma venereum. HIV incidence is a key indicator of epidemic control but is difficult to measure. Cross-sectional surveys, for instance general population surveys and antenatal surveys, may provide the necessary sample sizes, but are logistically difficult to implement and the results are not in real-time. Developing a point of care assay to detect recent infections may provide an alternative to monitoring recent infections. The centre is part of a multi-facility study that is currently assessing the utility of the test and specifically assessing the integration of the test as part of the routine workflow and the yield of recent infections. The results of the implementation will determine a national rollout programme.

Centre for Respiratory Diseases and Meningitis (CRDM)

The Centre for Respiratory Diseases and Meningitis (CRDM) is a resource for surveillance, diagnostics, expertise and research in communicable respiratory diseases and meningitis for South Africa and the African continent. CRDM is a WHO COVID-19 international, regional reference laboratory and provides technical support and training to many African countries. The centre generates data and provides expertise to the NDoH, healthcare providers, and regional and international collaborators to plan public health policies and programmes to respond adequately to respiratory and meningitis disease outbreaks. Data on the COVID-19 pandemic was used to advise several policy recommendations, such as those of the Ministerial Advisory Committee and the NDoH, including health system planning for emerging SARS-CoV-2 variants, and the implementation of non-pharmaceutical interventions and policies around the management of COVID-19 in schools.

Influenza vaccination guidelines were updated in light of new data on the effectiveness and safety when co-administering vaccines. CRDM was responsible for six category I NMCs, namely acute rheumatic fever, COVID-19, diphtheria, meningococcal disease, pertussis and respiratory disease caused by a novel respiratory pathogen, as well as two 'category II NMCs, Haemophilus influenzae type b (Hib) disease and legionellosis. The centre provided ongoing laboratory and epidemiological support to the NDOH for suspected diphtheria, pertussis, legionella and meningococcal disease. During the review period, the centre continued with response activities to the COVID-19 pandemic and its core surveillance function through syndromic and laboratory-based surveillance programmes. CRDM supported the National COVID-19 Incident Management Team, particularly in the epidemiology and laboratory streams. The centre produced regular COVID-19 surveillance reports, including the Weekly Epidemiological Brief, the Weekly Testing Summary and the COVID-19 Reproductive Number Report. Several detailed epidemiologic reports were also published in the Communicable Diseases Surveillance Bulletin. CRDM staff consulted on numerous expert committees and working groups for the WHO, Africa CDC and WHOAFRO. The centre was one of the founding members of the Network for Genomic Surveillance in South Africa (NGS-SA), that used routine genomic surveillance of SARS-CoV-2 to detect new SARS-CoV-2 variants as the pandemic progressed in South Africa and regionally. They were also responsible for detecting the Omicron variant in November 2021. CRDM obtained funding to conduct a range of COVID-19-related research activities that mainly focused on the burden of disease, transmission, seroepidemiology and viral sequencing. Additionally, the t team participated in numerous media engagements to educate the public about COVID-19 risks, ways to reduce transmission, as well as providing updates on the epidemic's progression.

Centre for Tuberculosis (CTB)

The core functions of the CTB involve the execution of TB surveys and population research, conducting laboratory-based public health surveillance of TB, and contributing to the advancement of TB epidemiology diagnostics and treatment, to help guide the South African policy.

CTB provided the National TB Programme with a bi-weekly analysis of Xpert MTB/RIF (Xpert) TB testing volumes, positive tests, positivity rate, and rifampicin-resistant rates to support the TB COVID-19 recovery plan. Xpert TB testing volumes recovered during 2021 have exceeded upper confidence bounds since November 2021.

The National TB Prevalence survey, a collaboration between the MRC, HSRC, NICD (CTB) and NDOH, planned to establish the actual burden of pulmonary TB disease in South Africa. It was conducted according to the international recommendations of the WHO Global Task Force on TB Impact Measurement. The survey began in mid-August 2017 and more than 35 000 individuals agreed to be part of the survey. 15 268 sputum samples were processed atand the findings of the study were presented on 27 January 2021. The overall prevalence of TB was 852 (95% CI 679-1,026) per 100 000, with a higher prevalence in males (1 094 per 100 000) versus females 675 per 100 000. Most of the survey cases were HIV negative, and 57.8% did not report any symptoms during specimen submission. Surveillance findings continue to be regularly analysed and reported to the national and provincial TB programmes. The weekly results for action (RfA) reports cover both drug-susceptible and drug-resistant TB. Quarterly reporting of the number of TB cases (both drug-susceptible and drug-resistant) nationally and further stratified by province and sub-district are ongoing, with automated reports being emailed to the relevant stakeholders at regular intervals. With support from the Global

Fund, enhanced TB surveillance reports were developed for nine priority TB districts to support the targeting of local interventions to improve the TB programme. The enhanced reports include detailed facility-level epidemiological, geospatial and trajectory analyses. Reports for 2021 Q1 to Q4 have been distributed and presented to stakeholders. Discussions are ongoing to solicit additional support and further expansion of the enhanced TB surveillance reports to all districts.

The development of the TB module on the Notifiable Medical Conditions (NMC) system has been a significant advancement on the public health surveillance and response front. The NMC-TB module allows users to capture cases electronically, which can then be viewed in near real-time by public health responders. The electronic capturing of cases removes the need for paper-based notification and reduces notification time and catching errors. This will ultimately reduce initial loss to follow-up among TB patients. The NMC-TB module will integrate clinical and laboratory notifications to provide a more accurate measure of the TB burden in South Africa. Internal piloting of the NMC-TB module has been completed, with the next phase of the piloting expanding to several healthcare facilities. The TB section of the GERMS surveillance focuses on participants with rifampicin susceptible TB, diagnosed at hospitals to detect isoniazid (INH) mono resistance and monitor the relative contribution of HIV/ART, TB preventative therapy (TPT) and pathways to care in reducing the incidence and achieving the expectations of the NDoH strategic plan. Hospitals in five provinces are included in the surveillance. The COVID-19 pandemic severely hampered the surveillance program, with only 267 samples received from the five provinces, of which 184 were culture positive and 14 (7.6%) found to be resistant to INH.

Centre for Vaccines and Immunology (CVI)

The Centre for Vaccines and Immunology provides epidemiological, virological and immunological support to the NDOH for vaccine-preventable diseases. The centre conducts testing and surveillance for poliovirus, measles, rubella, tetanus and viral hepatitis, all targeted for either eradication or elimination in the next few years. The target indicators for polio and measles, set by the WHO and the NDoH, guides detection and the sensitivity of the surveillance. In addition, the centre performs testing on wastewater samples to detect poliovirus and SARS-CoV-2. The centre remains committed to reaching the viral hepatitis elimination goals by 2030 and performs passive laboratory-based surveillance for hepatitis A, B and C by using data from the NHLS corporate data warehouse (CDW) and NMC.

The Poliovirus Isolation Laboratory serves eight countries within the southern African region for acute flaccid paralysis (AFP) surveillance. The countries include Angola, Botswana, Lesotho, Malawi, Mozambique, Namibia, Swaziland and South Africa, and performs environmental surveillance to Angola, Malawi, Mozambique, Namibia, and South Africa. The Poliovirus Regional Reference Laboratory is only one of two poliovirus sequencing laboratories on the African continent. During the period under review, 3 452 samples were processed for poliovirus isolation, namely 696 from South Africa and 2 756 from the remaining seven countries. For the period January to March 2022, the AFP detection rate in those under the age of 15-years in the country was 3.2 per 100000 population, meeting the WHO indicator of 2/100000, however below the South African target indicator of 4/100000. A wild poliovirus type 1 was detected in a sample from an AFP case in Malawi. Sampling,testing the community and household contacts, and collecting environmental samples from the area delivered no new cases. Heightened surveillance continues in the attempt to detect any circulation. Vaccine-derived poliovirus type 1(VDPV1) was identified in 53 samples received from cases in Madagascar and VDPV2 in 149 samples from cases of Burkina Faso, Democratic Republic of Congo, Ivory Coast, Liberia, Mali, Niger, Republic of the Congo, Republic of South Sudan and Sierra Leone, including two cases in Mozambique. Type 2 Sabin polioviruses were detected in 96 samples, the majority coming from countries using monovalent oral polio vaccine type 2 to halt VDPV2 transmission (Burkina Faso, Cote d'Ivoire, Mali, Democratic Republic of Congo, Republic of South Sudan, Republic of the Congo, Uganda).

The NICD partnered with the National Institute for Occupational Health (NIOH), Lumegen Laboratories, GreenHill Laboratories, Praecautio, Waterlab, Durban University of Technology, South African Medical Research Council-Tuberculosis (SAMRC-TB) platform and the Council for Scientific and Industrial Research (CSIR) in the South African Collaborative COVID-19 Environmental Surveillance (SACCESS) network to detect and geographically locate SARS-CoV-2 distribution in sewage. A total of 548 wastewater samples were processed for SARS-CoV-2 surveillance from sites in Gauteng, Western Cape, Free State, KwaZulu-Natal, Eastern Cape and the Northern Cape. SARS-CoV-2 was identified

in 498 samples (91%) and was quantitated using the optimised methodology to obtain copies of SARS-CoV-2 RNA/ml of wastewater. Quantitative PCR has documented increases and subsequent decreases in viral load in wastewater, correlating with clinical caseloads in each metropolitan area. In addition to testing, the NICD collates and reports results from 73 additional sites from SACCESS partners. The reports are compiled and shared with stakeholders every Friday, in addition to being published on an online dashboard. Mutations of the SARS-CoV-2 variants Beta, Delta, Omicron and C.1.2 have been successfully detected in wastewater using next-generation sequencing. SARS-CoV-2 is considered non-infectious from sewage samples, however the viral RNA remains detectable in raw sewerage. Sewage monitoring may provide additional information to the NDOH for planning geographically localised interventions.

The centre is the national and WHO Regional Reference Laboratory for measles and rubella testing and surveillance. Laboratory results (detection of measles-specific IgM antibodies, avidity of anti-measles IgG antibodies, RT-PCR and genotyping) are used with epidemiologic case investigations to diagnose acute measles infection. A total of 960 South African febrile rash samples were tested during the period under review, with five cases classified as confirmed measles cases, two classified as compatible, and eight cases still requiring classification (case notes pending). Measles genotype B3 was detected in a patient who had recently returned from the Democratic Republic of the Congo. No clusters of cases were detected. Only 20 rubella cases were identified via febrile rash surveillance. This is considerably lower than previous years and is likely resultant of lower health-seeking behaviour due to the COVID-19 pandemic and lower transmission because of social distancing and lockdown measures. For January to March 2022, South AFrica met the WHO indicator of a non-measles non-rubella discard rate of ≥2/100 000 population.

Division of Public Health Surveillance and Response (DPHSR)

DPHSR facilitates communication and data sharing between the national and provincial health departments and the NICD, and provides epidemiological input to other NICD centres through collaborative projects. It also provides support for surveillance, epidemiological and research activities, as well as outbreak responses. DPHSR incorporates the GERMS-SA surveillance programme, the Provincial Epidemiology Team (PET), the Notifiable Medical Conditions (NMC) Surveillance Unit and the Outbreak Response Unit (ORU), which works closely with the Emergency Operations Centre (EOC). Together, these teams contribute significantly to national communicable disease surveillance and response efforts by providing systems for rapid alert and notification of diseases of public health importance, as well as technical expertise to provinces, districts and healthcare workers within South Africa. In the past year, DPHSR has been integral to the national and provincial COVID-19 pandemic response by providing valuable epidemiological expertise in the field, and through creating data platforms that monitor trends in COVID-19 disease, testing, hospitalisations and deaths. Representatives from DPHSR attended the national COVID-19 Incident Management Team meetings with the NDoH. The centre also undertook several research activities in collaboration with NICD centres, national and international partners, and was responsible for the teaching and training of intern scientists, SAFETP students, public health registrars, and microbiology registrars from various universities across South Africa.

GERMS-SA collaborates with all NICD centres to provide a national active surveillance programme for laboratory-confirmed bacterial and fungal infections, complemented by enhanced surveillance at sentinel hospital sites. These data are used to inform and guide public health policymakers in their decisions. The PET comprises epidemiologists based in eight of the nine South African provinces, who support provincial health departments with epidemiological interpretation of TB, HIV, NMC data, and support outbreak investigation and management activities. During the COVID-19 pandemic, the epidemiological support brought about improved coordination and structured data flow, management and analysis processes within the operations of the provincial response teams. The PET also worked with stakeholders to improve data collection and reporting of COVID-19 related deaths, including post mortem COVID-19 testing on all natural deaths outside of hospitals. The NMC Unit provides a coordinated approach to the collection, collation, analysis, interpretation and dissemination of public and private sector NMC in South Africa through a real-time surveillance system, and provided information for targeted public health response, decision-making and resource allocation. Since March 2021, the accessibility of the NMC App had been expanded, making it available on all device platforms. The ORU and the EOC provided technical support to national, provincial and district health departments for all aspects of communicable disease outbreaks and control, and facilitated the coordination of outbreak detection, investigation and response activities with the appropriate NICD centres. The DATCOV hospital surveillance system informed understanding

of the evolution of the SARS-CoV-2 epidemic and served as an important alert mechanism for COVID-19 resurgences. The data have been used to inform hospital resource needs and provided vital insights into the severity and mortality during each wave of COVID-19.

National Cancer Registry (NCR)

The National Cancer Registry (NCR) is responsible for cancer surveillance, including the systemic collection, storage, analysis, interpretation, and reporting of cancer cases. National pathology-based cancer surveillance and implementation of population-based cancer registration are the primary roles of the NCR. For the year under review, the NCR also undertook childhood cancer surveillance as one of its primary roles. Within NHLS/NICD, the NCR is the only unit specialised in non-communicable disease surveillance. The information provided by the national pathology-based cancer registry offers an essential insight into the cancer landscape in South Africa. It affirms NCR's vital role in cancer surveillance, a growing non-communicable disease of importance in the country.

The NCR met all key performance indicators for the year, including publishing two national cancer incidence reports. The population-based surveillance team made every effort to catch up on data collection, despite the challenges faced in 2020 due to the COVID-19 pandemic. With hospital wards closed, outpatient clinics suspended, and restrictions on the movement of surveillance officers, high-quality and complete cancer data collection were hindered. The overall case finding and data collection for 2020 decreased by 33.3% compared to 2018.

The newly established National Childhood Cancer registry published the first report on childhood cancer incidence (from birth to 14-years old) for 2018. There has beens a need for accurate childhood cancer estimates globally, but this is particularly difficult and scarce in sub-Saharan Africa. Annual reports of childhood cancers are the first step toward improving the reporting of childhood cancers and raising awareness of the incidence.

In the year under review, cancer incidence reports for 2018 and 2019 were published on the NCR website (https://www.nicd.ac.za/centres/national-cancer-registry/). In 2019, there was a 5.58% increase in cancer cases compared to 2018.

A 10-year cancer trend analysis (2010-2019) report was produced, providing a comprehensive and up-to-date overview of the trends in cancer incidence in South Africa for the past decade. The effect of the enactment of Regulation 380, which made cancer reporting obligatory in 2011, is reflected by the increase in cancer incidence between 2010 and 2012, as illustrated in the report. The key findings of the report are that breast cancer incidence among women increased between 2010 and 2019, and is still the leading cancer diagnosis among women in South Africa. There was also a significant increase in prostate cancer incidence in men from from 2010 to 2019.

Ekurhuleni population-based cancer registry (EPBCR) report details the fourth year of population-based cancer registration in Ekurhuleni metropolitan municipality, Gauteng province of SA. This includes cancers that were diagnosed between January and December 2020. Data collection for these cancers were conducted in 2020 and 2021. The unprecedented COVID-19 pandemic in 2020 posed many challenges to public health programmes globally, and the EPBCR was no exception. The overall case finding and data collection for 2020 decreased by 33.31% to 3 131, compared to 4 695 in 2018. Some of the challenges were:

i) restricted access for EPBCR surveillance officers to collect cancer data in health facilities during the lockdown;
ii) the misinterpretation of the Protection of Personal Information Act (POPIA), resulting in facilities being less willing to report cancer data; and
iii) closure of Charlotte Maxeke Johannesburg Academic Hospital (a significant data source for EPBCR) due to the fire in 2021.

Despite the challenges encountered by the EPBCR surveillance officers in data collection, the report provided valuable information for key stakeholders to guide decision making, planning of cancer initiatives and intervention programmes, and essential data for evaluation of health interventions.

A first for South Africa was publishing a childhood cancer registry as a standalone report using the International Classification of Childhood Cancers Third Edition (ICCC-3). A total of 975 cancers were diagnosed in children from birth to 14-years of age in South Africa in 2018. This equated to an overall age-standardised rate of 59.8 cases per million (95%CI: 48.6-73.2). We found that the most common cancer group was diagnosed with leukaemia and followed global trends. The second most common cancers were lymphomas, aligning with previous reports on childhood cancer incidence from the country. Almost half of all the cases (n=441) were diagnosed in children aged from birth to 4-years of age. Most of the report's results were comparable to results from within the region and global trends.

Deputy Director's Office

The exceptional and protracted demands of the COVID-19 pandemic emphasised the importance of transversal functions of Biosafety and Biosecurity, Communication, Information Technology, Field Epidemiology, and Occupational Health services. Despite challenging conditions, the teams remained resolute in achieving future-orientated goals. The Division of Biosafety and Biosecurity (DBB) championed the secure operation of the NICD`s high and maximum containment laboratory infrastructure under the Biorisk Management umbrella for biosafety biosecurity and biocontainment engineering. DBB has been instrumental in developing several policies that include the Regional Training and Certification Program and a Regulatory and Certification Framework for Institutions Handling High-Risk Pathogens for Africa. This work has been subject to rigorous review, including numerous regional consultative meetings convened by Africa CDC, with the DBB team now leading the development of training materials with the support of a sub-committee of the NIOH and WITS Steve Biko Centre for Bioethics. As part of efforts to support the delivery of COVID-19 diagnostic services, DBB facilitated the biocontainment enhancements of the NHLS`s mobile laboratory fleet. The collaboration with Canada's Weapons Threat Reduction Program was to support the NHLS COVID-19 mobile diagnostic laboratories to enhance the national capacity to respond to the pandemic. Practical completion of the Regional Diagnostics Demonstration Centre (RDDC) construction was achieved in March 2022. The 600m2 training facility, built-in collaboration with the US Defense Threat Reduction Agency (DTRA), is a state-of-the-art training centre that provides secure and dedicated laboratory space for training in routine diagnostic procedures. The design was constructed as an assimilation centre to mimic a real laboratory environment, enabling trainees to experience the laboratories' appropriate infrastructure and operation that adhere to biosafety and biosecurity standards.

During the period under review, the Communications Unit remained committed to fulfilling its vision of being a premier source of trustworthy and fact-based information for its various public stakeholders, including healthcare providers and media professionals. In response to the ongoing COVID-19 epidemic, the team drafted and syndicated media statements and public health alerts and was instrumental in releasing daily and weekly COVID-19 surveillance reports. The NICD website remains a reliable source of communicable disease information and holds a significant repository of content that requires frequent reviewing and updating. Since 2019 the website has recorded more than 45.2 million page views, of which 15.1 million views are attributed to the year under review. Furthermore, over 10.2 million users have frequented the website since 2019, of which 4.1 million users account for the past financial year. The volume of growth experienced on social media is unprecedented, and testimony to the quality of the content shared across its various platforms. Since 2019, each platform has enjoyed notable year-on-year growth. Twitter followers have increased by 113%, YouTube subscribers by 444%, and LinkedIn and Facebook communities have recorded an astounding growth of 1 654% and 3 640%, respectively.

The Information Technology team focused on improvements to the automation of COVID-19 laboratory tests for both public and private sectors, whilst maintaining service levels above 98%. A soft launch of the re-engineered Notifiable Medical Conditions system with further developments are underway. A highlight was the successful implementation of the high-performance clustering system for the sequencing centre that enabled the rapid throughput required for sequencing data.

The South African Field Epidemiology Training Program (SAFETP) uses an established applied epidemiology curriculum, providing an accredited Master of Science (MSc) degree from either the UP or Wits with mentored practical field experience. In addition to the Advanced tier, SAFETP offers the Frontline and Intermediate tiers. The Frontline tier, launched in 2016, is a three-month in-service training program and the first step in the three-tiered FETP model of

training. The Intermediate tier, launched in November 2021, is a nine-month in-service program designed to provide health professionals with the essential skills used in surveillance. The program has more than 104 graduates employed in various sectors, such as the public sector or ministry of health, private sector, Africa CDC, US CDC (in-country office), and the WHO. 42 graduates are employed by the NICD and are located in the provinces or at the NICD centres. Currently, the program has 29 residents.

The significant impact of SAFETP in this reporting period was the involvement of graduates and residents in COVID-19 related surveys and research of the SARS-CoV-2 school transmission study, in collaboration with the South African Medical Research Council (SAMRC), the Western Cape Department of Health, the Department of Basic Education and the University of Cape Town.

Sequencing Core Facility (SCF)

The Sequencing Core Facility is a transversal facility that supports all the NICD centres' next-generation sequencing (NGS) needs by providing sustainable solutions, thereby enabling the detection of outbreaks or epidemics at an early stage in order to effectively respond to or anticipate imminent outbreaks or epidemics. The Illumina Sequencing Core facility has received SANAS 17025 accreditation for Illumina sequencing and whole genome sequencing. The SCF supported the Africa CDC, ASLM, and Africa PGI for SARS_COV2 sequencing for African countries including Namibia, Sudan, eSwatini, Lesotho and Mauritius. With the support of the Fleming fund/SEQAFRICA funding bacterial sequencing (***Salmonella*** sp, ***E. coli, S. typhi, P. aeruginosa, K. pneumoniae***) was performed for participating African countries to monitor MLST, AMR and virulence genes.

NATIONAL INSTITUTE FOR OCCUPATIONAL HEALTH

Dr Spo Kgalamono
Executive Director

The NIOH is recognised as a centre of excellence for occupational health and functions as a national and regional source of knowledge and expertise for the South African government, industry and labour, the Southern African Development Community (SADC) countries and the African region. The Institute plays a significant role in supporting the government's occupational health efforts. 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.

The period under review was once again dominated by the COVID-19 pandemic, which continued to impact workplaces across South Africa and the globe. Under the leadership and continued support of the NHLS, the NIOH had numerous highlights in the area of Occupational Health and Safety (OHS), and pivoted itself to be recognised as a leading organisation in occupational health amidst the backdrop of the global pandemic. The Institute's focus shifted to providing a collective outbreak response within the public health and OHS fraternity, which required constant adaptation to workplace responses as new OHS information came to light.

Consequently, the NIOH participated in new OHS knowledge generation, as well as design and adaptation of OHS tools to assist workplaces in responding to the effects of the COVID-19 pandemic. Numerous audits and training activities were conducted to support economic activities across various occupational groups in different sectors. This was achieved through engagements with key stakeholders in South Africa and the region.

The multidisciplinary team of the Institute participated in research at a national and global level in support of innovative programmes to assist vulnerable workers. In the process, the NIOH collaborated with many key workplace role players locally, nationally and internationally. This in turn contributed to the Institute's gaining a new body of knowledge that enabled the translation of research into policy and relevant practice.

Highlights

There were some notable developments in the OHS in South Africa during the period under review, where the NIOH played a significant role. A number of staff members represented the NIOH at key high-level decision-making technical committees, including the National Economic Development and Labour Council (NEDLAC), the NDoH, and the Department of Employment and Labour (DEL), drafting and revising specific occupational health legislation and guidelines – both in the formal and informal economy.

Year after year, the NIOH's specialised laboratories maintained their QMS Accreditation. The Institute is the only entity in South Africa that has acquired four different quality management systems. ISO 15189 (Medical Laboratories), ISO 17025 (Testing and Calibration Laboratories), ISO17020 (Conformity Assessment for Inspection Bodies) and ISO 9001 and has also been able to provide pre-SANAS internal audits, training and support to NHLS laboratories, including Proficiency Testing (PT) Scheme guidance to staff.

During the reporting period, the Occupational Health and Safety Information System (OHASIS) has proven to be an invaluable OHS management tool and continues to be adapted to cater to the new challenges posed by COVID-19 and the unique needs posed by the laboratory environment within the NHLS. The system provided weekly statistics for the NHLS EXCO and COVID-19 Compliance Officers to assist with decision-making related to monitoring and management. OHASIS supports surveillance and compliance with OEHS legislation and provides information for research.

The developments to 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 notification to an identified health worker; the provision of all COVID-19-related information in dashboards; the facility for the recording of all COVID-19 vaccinations, tests and results; the facility for recording COVID-19 and related training in the Workforce Health module; and the capability to capture COVID-19 health care waste. Beyond the NHLS, a number of local and international organisations have expressed an interest in implementing the system, some of which are at an advanced stage of securing the software.

The NIOH had enhanced its brand identity and positioned itself as a critical touchpoint for quality OHS guidance and information dissemination at a time when many workplace stakeholders required access to reliable COVID-19 information, placing emphasis on the value and importance of OHS provision within workplaces. The institute's digital footprint was also increased through the effective utilisation of the social media platforms Twitter and YouTube, which saw sustained growth and an increased viewership base. This, coupled with strategic media engagements and interactions, resulted in the image of the NIOH being tremendously and positively enhanced in the public domain during the period under review. These communication channels provided the opportunity for networking on a global scale, assisted with targeting specific stakeholders through tailored communication, and provided diverse public relations platforms to share information. In addition, the NIOH newsletter (OccuZone) continued to be used as a medium for sharing information about the Institute's activities. This quarterly publication details current research outputs, specialised service delivery, and the teaching and training activities of the Institute.

COVID-19 activities

Owing to the pandemic, the NIOH had to put on hold a number of specialised, discipline-specific services it provided to many industrial sectors and government departments in order to provide national industry COVID-19 advisory support. Despite this shift in focus, the pandemic provided numerous opportunities for NIOH that emphasised its value well beyond traditional occupational health. During the reporting period, the NIOH provided their professional and technical knowledge to a variety of advisory service activities. These platforms included the NDoH OHS Workstream and Private Public Labour group; NEDLAC and subcommittees including behaviour change communication; Wits School of Public Health Return to School Committee; Surveillance system for worker's policy and technical teams; Care for the caregiver; and Return to mining committee.

In collaboration with academia and the leadership of the NDoH, the NIOH contributed to the COVID-19 Regulations, Directions and Guidelines relating to Workers and Workplaces. The NIOH dedicated workplace advisory hotline, specifically for occupational health professionals, employees, employers and the regulator, was maintained and enhanced to address OHS needs across the country. Queries from the hotline were used to form the basis for some of the webinars that catered for various occupational groups across different sectors.

Training events were used to equip the industry with the tools required to protect and promote workers' health and safety, including the safe return to work during the pandemic. In the period under review, 30 webinars were conducted, with over 11 225 participants being trained on COVID-19 topics. Cumulatively, this brings the total number of webinars conducted since the start of the pandemic in March 2020 to 98, with 52670 participants trained. A centenary webinar is planned for the first quarter of the new financial year to reflect on our collective outbreak response within the public health and OHS community.

The members of the NIOH OH Outbreak Response Task Team prioritised enhancing access to reliable information to curb misinformation and disinformation. This initiative resulted in the creation and dissemination of numerous fact sheets, posters and infographics relating to various aspects of the pandemic that impacted workplaces. As legislation changed, several posters and fact sheets were updated during the reporting period. All these materials are accessible via the NIOH's zero-rated website. Towards the end of the financial year, NIOH was finalised its E-Learning Platform, which will be launched in the new financial year.

Research

Our goal, as a national institute for OH, is to produce new knowledge and innovation in an effort to prevent ill health and injury and promote good health. The research, therefore, remained a priority for the NIOH and focused on the prevention of workplace exposure with specific reference to hazardous biological agents. The individual departmental reports that follow illustrate a large and varied inter-disciplinary research programme covering many issues central to the advancement of workers' health and the health of communities living around workplaces. The topics of the scientific articles published over the year reveal the large variety of research needs in OHS in the country. In total, the few researchers at the NIOH managed to publish 30 articles in peer-reviewed journals and supervise 35 postgraduate students on various projects.

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 made to increase the publication of surveillance reports.

The national Occupational Health Surveillance System (OHSS), initiated in October 2020, monitors COVID-19 infection across workplaces in South Africa and provides insights/data into understanding the post-infection and return-to-work health outcomes of employees. The OHSS, therefore, 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 to inform appropriate interventions (e.g., policy, programmatic, resources). With the existing surveillance system, the NIOH intends to strengthen OH reporting for occupational diseases and to create a flexible surveillance system that can be linked to other national databases for comprehensive reporting. The system is the foundation on which surveillance for all occupational diseases and injuries will be based.

In addition, several other surveillance initiatives continue within the Institute. As per statutory obligation, the Pathology Disease Surveillance (PATHAUT) report was also published and is accessible on the NIOH Website. The Institute produced several surveillance reports, including the COVID-19 Monthly Sentinel Hospital Admissions Surveillance for Health Care Workers (HCWs), NHLS Tuberculosis Surveillance Reports, the 2020 Asbestos Surveillance Report, Occupational Allergies Surveillance Report, and the Occupational Medicine Clinic Surveillance Report.

International liaison

During the reporting period, the NIOH finalised the renewal of the MoU with the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention (NIOSH-CDC) in the USA and maintained its status as a World Health Organization (WHO) Collaborating Centre (CC). This is a recognition and affirmation of the NIOH's achievements in supporting the occupational health programmes of the WHO and the extension of opportunities for partnerships and projects with the network of collaborating centres around the world. The NIOH had a prominent role in the WHO's programme on vulnerable workers, such as those in the informal economy.

Through dedicated collaboration and networking efforts with key international agencies, the NIOH fostered strong international relationships. These included the WHO; the International Labour Organization (ILO); the African Union Development Agency (AUDA-NEPAD); the International Commission on Occupational Health (ICOH); the NIOSH-CDC; USA; the Health and Safety Laboratory of the UK; Workplace Health Without Borders (WHWB) and the Organisation for Economic Co-operation and Development (OECD).

Moving forward - the future of the world of work

The world of work is undergoing rapid transformations that will persist and potentially intensify in the future. These include economic, environmental, technological, and demographic shifts that will change perspectives on how we work. The COVID-19 pandemic has elicited the need to interrogate, adapt and change our ways of working and interacting. According to the NIOSH-CDC Future of Work Initiative, employers and employees are confronted by emerging and complex issues such as changing employment patterns and relationships, labour recruitment and retention in competitive markets, an ageing workforce, gender and racial inequalities, and job loss due to technological innovations. Aspects of unemployment and worker health may need consideration by the Institute moving forward as a new area of research in collaboration with other partners. The informal economy, which is large already, will probably continue to expand rapidly, and the NIOH's programmes in this economic sector will need to be geared to respond to the growing needs. All of working life may be altered to some extent, and the work-related health effects that accompany these changes – both the bad and the good – will need to be assessed and carefully managed.

As a national institute, it is therefore incumbent on us to find a careful balance of all these occupational safety and health issues to meet the challenges and opportunities presented by the future of work. The Institute will interrogate and try to understand the implications of these new work scenarios to translate effective interventions into practice for employers so that they may safeguard the health and well-being of their workforce. Working with stakeholders and partners, we can build the necessary resilience as a sector of strengthening and renewing our approach and response to the growing and changing needs of OHS, all with the goal of protecting employees and employers from occupational hazards and their consequences.

SUPPORT SERVICES PERFORMANCE

INFORMATION AND COMMUNICATION TECHNOLOGY

Sibongiseni Hlongwane
Chief Information Officer

Infrastructure and Operations

The MPLS contract was awarded to MTN in mid-2021. All 248 NHLS sites successfully migrated to MTN from DV8 by the end of July 2021. With several challenges experienced from site surveys, link building, equipment swops out from the previous incumbent, link cutover, power outages, and floods in April, the project has been highly affected and delayed. NHLS, together with MTN senior management, put up an intervention plan to quickly track the progress of the project.

The scope update to date is as follows:

There are 248 sites planned for infrastructure to be built and upgrades implemented across various mediums, including fibre, LTE and VSAT. A total of 320 links were initially planned due to redundancy requirements at some sites, hence having dual mediums. 311 links' builds or upgrades are in progress, i.e., work has started. Thus far, 32 of the initial scope of 320 links are planned for the third infrastructure due to the current infrastructure or precinct. Initial surveys have presented challenges. Forty-five links are still being replanned. Rollout progress, including new link builds and upgrades, is at 46% completion. Cutover progress has improved and is now at 44% completion. The Year to Date project is behind schedule, with 144 links completed. Nine links were cancelled or requested for relocations, and a variance of 167 is outstanding (legacy contractual reasons, weather conditions, vandalism, power issues, cabinet issues). One hundred ten links have been cutover with several challenges reported pre- and post cutover.

Phase 2 of the local area network (LAN) refresh project has completed the installation of network switches for phase 1. 49 sites, including data centres, with 248 switches installed. Access points for WIFI installed are 107 out of 150. Major changes were made in the two data centres where the new core switches, routers and next-generation firewalls were installed. This improved the security and throughput speeds within the LAN. The procurement of network cabinets in the North West, Western Cape, and Northern Cape has been completed; Free State and Gauteng are currently underway, while Limpopo, Mpumalanga, KwaZulu-Natal, and Eastern Cape have required intervention. An order has been raised with Vodacom for routers for the SANREN environment.

Server and data storage infrastructure equipment has been upgraded in both data centres. The new infrastructure hosts our Microsoft, ECM and other key systems except for CDW and Oracle. The LIS environment is also getting an upgrade, and orders for equipment have been placed. The old equipment being replaced is now being utilised for development and testing platforms. Installation and migration of environments have been successfully completed.

Microsoft Office 365 has been successfully rolled out to five hundred officials. This intends to minimise the downtime for the officials, and their emails will be archived outside the NHLS environment, thus relieving the data capacity constraints.

Applications and Systems

Both the Oracle and ECM teams are working on the integration of Oracle and ECM. This project is the foundation of our digitisation endeavour through Accounts Payable automated invoice capturing and electronic documentation of the Procure to Pay process. Remote evaluation of tenders has been successfully implemented while it is dependent on the network capacity.

Automate Document Approval process (deviations and memos); this solution is operational with support provided to NICD and NHLS. More than 100 deviations have been approved via solution thus far.

ECM is developing Enterprise Business Workspaces and has completed projects for the Office of the CEO, Finance, Risk Management and Internal Audit, IT, Communication, Marketing and Public Relations, including Laboratories in Gauteng and Western Cape. There are 24 active out of 54 business workspaces for Corporate. There are five active out of 430 business workspaces with laboratory services.

QR codes on COVID-19 reports have been successfully implemented. This has become mandatory for international flights out of the country. This allows for verification of information by reading QR codes.

System availability for all systems, including TrakCare and Oracle, has met the SLA for the period. TrakCare slow responses have improved, while the NHLS, together with InterSystems, is looking at the design and architecture of the system to see where further improvements can be made. CDW reports to the provinces have been delivered successfully with minimal delays.

The ISC COVID-19 Order Entry System is in progress where sessions with developers have been initiated to refine scope. Forensic Chemistry Laboratory (FCL) migration in process, financial and human resources data has been received from NDoH and has been incorporated into our Oracle system. New equipment has been deployed to FCL sites and is awaiting network connectivity into the NHLS MPLS. The FCL will migrate from their LIS and will be using a separate instance of the TrakCare Laboratory. Development of the interface is in progress for Lumira Analysers. Solution design in progress, basic features to be included in OEM system development for Specimen Tracking.

Billing interface improvement and full billing improvement processes are under design where ISC, Oracle and MediSwitch are involved. Solution design is in progress for medical aids on Trakcare, with technical meetings being conducted.

The scheduling of xECM concurrent programmes for daily workspace creation and document archival is in progress. Seven out of eight workspaces were successfully created. User synchronisation is completed. Project close-out activities are in progress.

CDW is initiating the process of moving Netezza extracts to MicroStrategy and updating GPS Coordinates on Dim Facilities. Incorta POC for dashboards for the stock management system on Oracle. Procure Aginity Pro licences.

Business intelligence initiatives within CDW are as follows: security review (security groups and privileges) self-service portal, disaster recovery implementation SOP, laboratory performance dashboards user manuals, BI backup and restore SOP, business glossary, Netezza extracts to MSTR subscriptions, ESRI Licence Renewal RFQ, and customer surveys.

Governance and Reporting

Information Security and Governance policies have been reviewed, and new policies have been developed due to gaps identified by internal audits and recommendations from Risk. The approval process is under way for the new policies.

The vulnerability scan on the Oracle environment has been completed. The results are being analysed, and a report is being prepared. Weak cipher suite remediation is ongoing in the LIS department. The process of remediating high and medium-risk vulnerabilities that were detected in the Microsoft and LIS environments is continuing. Support calls have been logged for the vulnerabilities to be remediated. An ISO review was conducted during the year, and we are now gearing up for preparations to get the unit ISO certified.

Client Support Services

The IVR System (Call Centre System) is currently under implementation. This is to ensure that the IT service desk functions properly with all calls being monitored. The ITSM service desk system for call logging is pending approval. This will ensure that IT incidents and requests are well managed as per IT best practice and can be reported in detail. The tender for the multipurpose devices (printers, scanners, copiers) was cancelled due to the expiry of RT3 and will be re-advertised in the new financial year.

Conclusion

The second year of COVID-19 has not been an easy one again. We have implemented a number of projects that are currently in progress, and resource availability has been one of the key factors. Resource constraints from both IT and procurement have had a negative effect on the process flow. There is a very high expectation from IT to provide better services and with a shorter turnaround time. Reliability and high availability are very key for business, and IT has all available hands-on deck to ensure this.

COMMUNICATION, MARKETING AND PUBLIC RELATIONS

Mzimasi Gcukumana
Senior Communication Manager

The Communication, Marketing, and Public Relations department has played a crucial role in alerting both staff and the public through the media about COVID-19 threats, providing guidance for protective action, motivating compliance, and encouraging internal audiences to heed calls for vaccination.

For internal audiences, communication channels such as the intranet, notice boards, and posters have been a critical tool in this process and have facilitated the rapid dissemination of messages down to individual-level engagement. Message dissemination and amplification have been a necessary precursor to reaching audiences as well as inspiring action.

For internal communication, the department used channels available to communicate new developments in the organisation. In addition, the department was key in communicating both local and international commemorative days. These were used as a messaging vehicle for management to send out organisational messages to all employees to provide them with a better understanding of the purpose, goals and directions of the NHLS.

For external stakeholders (media), the NHLS was able to reach its targeted stakeholders by leveraging earned media – publicity gained from methods other than paid advertising. This was done through media queries received during the year under review. All the media queries were attended to timeously, and no deadlines were missed.

Annual report

The department successfully produced the 2020/2021 NHLS Annual Report in line with the National Treasury guidelines by engaging with various other departments. The department's role is to coordinate and consolidate inputs from the organisation. In addition, the department compiled the NHLS Annual Report presentation tabled at the Parliamentary Health Portfolio committee, as per Treasury guidelines.

Branding

As the custodian of the NHLS brand, the department continued to uphold the brand identity of the organisation with the various stakeholders. As a precursor to the national brand audit, auditing was performed in the Gauteng region to identify branding gaps. A report has been compiled.

The department continued to support all regions with the required branding collateral for COVID-19 and awareness.

Events

The department facilitated two high-profile visits in the financial year under review. In May 2021, the NHLS hosted the Federal Minister of Health, Germany, the Honourable Jens Spahn.

The department also played a crucial role in ensuring that the NHLS Organising Committee delivered a successful virtual Pathology Research and Development (PathReD) Congress hosted in August 2021. The Congress is a biennial meeting inaugurated in 2015 to share scientific knowledge, build expertise, strengthen capacity, and hone the skills of emerging professionals in the pathology and public health disciplines.

In December 2021, the department facilitated the visit by the Ambassador of France to South Africa, His Excellency Aurélien Lechevallier. The Ambassador was on a mission to learn more about the work of the organisation in dealing with COVID-19, especially the new Omicron variant, how the NHLS through NICD collects data and research on HIV and TB.

PART C
GOVERNANCE

Adv Mpho Mphelo
Company Secretary

INTRODUCTION

Corporate governance embodies processes and systems by which entities are directed, controlled, and held accountable. In addition to the legislative requirements based on the NHLS enabling legislation, corporate governance guidelines in terms of King IV and the prescripts of the PFMA, the Parliament, the Executive Authority, the Accounting Authority, and the Accounting Officer of the entity are responsible for corporate governance in the entity.

The NHLS confirms that its structures, systems, processes, and practices are reviewed regularly to ensure compliance with legal obligations, use of funds economically and efficiently, and sustained performance of the services offered.

PORTFOLIO COMMITTEES

The Parliamentary Portfolio Committee on Health exercises oversight over the service delivery performance of the public entities reporting to the Health Department.

The NHLS appeared before the Parliamentary Portfolio Committee on Health on the dates set out below:

Table 1: Portfolio committees' meetings

Date	Parliamentary Structure	Activity/Focus
6 May 2021	Portfolio Committee on Health	Presentation of the Strategic Plan, Annual Performance Plan (APP) and Budget 2021-2022 Financial Year.
05 November 2021	Portfolio Committee on Health	Presentation of the Annual Financial Statements and Annual Report for 2020-2021 Financial Year.
19 April 2022	Portfolio Committee on Health	Presentation of the Strategic Plan, Annual Performance Plan and Budget for 2022 -2023 Financial Year.

Executive Authority

The Minister of Health is the Executive Authority of the NHLS, as defined by the PFMA, No. 1 of 1999. He is responding to the appointment of Board members in line with section 7 of the NHLS Act, No. 37 of 2000.

Report of the Accounting Authority

The Accounting Authority submits its report for the financial year ending on 31 March 2022.

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 practices.

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 with 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 service's strategic direction.

The various Board committees 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 with the external and internal auditors. Furthermore, the Board, its committees, and individual Board members may engage independent counsel and advisers upon request and at the discretion of the Board.

Board composition

The Accounting Authority is a Unitary Board comprised of 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 NHLS Act No. 37 of 2000, the Board should comprise twenty-two (22) members, including the CEO, Chairperson and Vice-Chairperson of the Board. The Minister of Health has appointed a chairperson and a vice-chairperson in terms of section 9 of the NHLS Act.

The members of the entity during the year and to the date of this report are as follows:

Table 2: Board composition

#	Name	Constituency	Date of appointment	Term ends	Chairpersonship/ Position in the NHLS
1	Prof Eric Buch (Chairperson)	Minister of Health	01January 2017 Re-appointed 01 May 2021	01 May 2024	Board and GSEC
2	Prof Jeffery Mphahlele	Minister of Health	08 May 2020	08 May 2023	
3	Dr Gerhard Goosen	Mpumalanga Province	01 November 2015 Re-appointed 01 November 2018	01 November 2021	Acting Chair: FinCom
4	Dr Kamy Chetty	Chief Executive Officer	04 October 2017		EXCO/OPCO
5	Dr Balekile Mzangwa	Free State Province	18 November 2016 Re-appointed 18 January 2020	18 January 2023	
6	Mr Jonathan Mallett	Northern Cape Province	18 January 2020	18 January 2023	
7	Ms. Sphiwe Mayinga	Public Nominee: Legal	20 April 2017 Re-appointed 08 May 2020	Resigned 01 January 2022	RHRC
8	Prof Mary Ross	Gauteng Province	01 September 2015 Re-appointed 14 September 2018	14 September 2021	RIC
9	Ms Nicolene Van der Westhuizen	Western Cape Province	01 May 2018 Re-appointed 19 October 2021	18 October 2024	
10	Prof Thanyani Mariba	Limpopo Province	18 January 2020	18 January 2023	NAPC
11	Dr Siseko Martin	Eastern Cape Province	08 May 2020	08 May 2023	
12	Dr Naledzani Ramalivhana	Public Nominee: Health Research/Epidemiology	08 May 2020	08 May 2023	
13	Mr Michael Sachs	Public Nominee: Economics, Financial Matters/Accounting	08 May 2020	08 May 2023	ARC
14	Prof Mpho Kgomo	Council on Higher Education (CHE)	08 May 2020	08 May 2023	
15	Mr Koena Nkoko	SALGA	08 May 2020	08 May 2023	
16	Dr Lesley Bamford	National Department of Health	08 May 2020	08 May 2023	
17	Mr Nick Buick	Minister of Health	19 October 2021	18 October 2024	
18	Dr Mahlane Phalane	Mpumalanga Province	01 November 2021	31 October 2024	
19	Mrs Penelope Msimango	KwaZulu-Natal Province	01 November 2021	31 October 2024	
20	Prof Tivani Mashamba-Thompson	Council on Higher Education	19 November 2021	18 October 2024	

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, has carefully considered the outside chairpersonships that members hold. The relative size and complexity of the companies in question have been taken into account. The Board members are satisfied that they have the ability and capacity to discharge their duties.

The qualifications and external directorships of the NHLS Board members are disclosed in the table on page 127 to 128:

Table 3: Board members qualifications and external directorship

Names	Qualifications and external Directorships
Prof Eric Buch	**Qualifications** MBBCH, MSc (Med),FFCH(cm)(SA), Diploma in Tropical Medicine and Hygiene(DTM&H),DOH **Directorships** The Colleges of Medicine of South Africa (CMSA)
Prof Jeffrey Mphahlele	**Qualifications** BSc, BSc Med Hons, MSc, PhD **Directorships** CEPI, EDCTP, GloPID-R, SAHPRA and Poliomyelitis Research Foundation NPC.
Prof Mary Ross	**Qualifications** BSc(HONs), MBCHB, Dip (Data metrics), Dip (Health Admin, DTM & H, DPH, DOH, FCPHM, FOM (UK), FPH(UK), FFTM (RCP &S GLASGOW), FACTM(Australia) **Directorships** None
Mr Nick Buick	**Qualifications** BCom, Cert Theory of Accounting, CA(SA) **Directorships** Medres (Pty) Ltd
Dr Mahlane Phalane	**Qualifications** MBBCH, Cert (Clinical Mngt), Cert (HIV Mngt), Dispensing Course, MBA, MSC Sports Med, ABIME cert medical examiner, Adv Trauma Life Support, Basic Life Support, Basic Surgical skills. **Directorships** Mappleman (Gen Del), Amdiler (Gen Del), Hlwape (Gen Del0 50% partnership, Tladi Family Trust, Mpumalanga DoH full-time employment
Prof Tivani Mashamba-Thompson	**Qualifications** Foundation Degree, Hons (Applied Biomed SC), Post Grad (Biomed SC), Masters (Pharmaceutical SC), PhD (Public Health), Grad Cert (Clinical Research) **Directorships** None
Dr Balekile E Mzangwa	**Qualifications** MBCHB, PGDip Health Management **Directorships** None
Mrs Penelope Msimango	**Qualifications** Dip: General Nursing, Dip: Midwifery, BA Cur (Nursing Education and Com Health), Adv Dip (Midwifery and Neonatal Nursing Sc), Adv Dip (Health Management), Masters in Public Health (in progress) **Directorships** None
Ms Sphiwe Mayinga	**Qualifications** BProc, LLB, LLM, MAP, SLDP, Advanced Banking Law, Corporate Governance, Compliance Management **Directorships** Tiyisela Construction, UNISA SBL (Member of Risk and Audit Committee and Chairperson of Remuneration and Human Resources Committee)
Dr Kamy Chetty	**Qualifications** MB. ChB, MSc URP, FFCH **Directorships** Hospice Wits

Names	Qualifications and external Directorships
Mr Jonathan Mallett	**Qualifications** Nat Cert Medical Lab, Nat Dip Medical Lab, B. Tech, Adv Health Management Cert, BA **Directorships** None
Ms Nicolene Van der Westhuizen	**Qualifications** National Diploma in Clinical Pathology and Histo Pathology **Directorships** None
Prof Thanyani Mariba	**Qualifications** MBChB, FCP(SA), FRCP(London) **Directorships** None
Dr Siseko Martin	**Qualifications** BSc, BSc Hon, MBChB, Dip (DTM&H), FCPath, MMED **Directorships** Dietrich Voigt Mia, Dr WJH Vermark Inc
Dr Naledzani Ramalivhana	**Qualifications** Dip Personnel and Training Management, Adv Dip Occupational Health and Safety, NDip Biomedical Technology, BSc Hon, MPH, MSc, PhD. **Directorships** Afroherbal Science Laboratories.
Mr Michael Sachs	**Qualifications** 'O' Levels (GCEE), 'A' Levels (GCEE), 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, Head of the SAGES HoD Academic Head
Mr Koena Nkoko	**Qualifications** Dip Comp Nursing, AdvDip Management, PGDip Health Management, B. Tech OHN and Nursing Management, MPH, MBA **Directorships** None
Dr Lesley Bamford	**Qualifications** MBChB, B. Soc.Sci, 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 on the same committee. The table below indicates the changes to Board membership that took place during the financial year under review:

Table 4: Changes in Board membership

Name	Constituency/Representing	Date of appointment/ * reappointment	Date of resignation/ * retirement
Prof Mary Ross	Gauteng Province	14 September 2018	14 September 2021
Ms Sphiwe Mayinga	Public Nominee: Legal	08 May 2029	01 January 2022
Dr Gerhard Goosen	Mpumalanga Province	01 November 2018	01 November 2021
Mr Nick Buick @	Minister of Health	19 October 2021	
Mrs Penelope Msimango @	KwaZulu-Natal Province	01 November 2021	
Prof Tivani @Mashamba-Thompson	Council on Higher Education	19 November 2021	
Dr Mahlane Phalane @	Mpumalanga Province	01 November 2021	
Mrs Nicolene van der Westhuizen #	Western Cape Province	19 October 2021	

LEGEND:
@ = New-appointments
 # = Re-appointments

Committees of the Board

The Board, as the Accounting Authority, takes full ownership of the overall decision-making across the entity to ensure it retains proper direction and control of the NHLS.

The Board has delegated certain powers to the CEO and management but has reserved certain powers exclusively for the Board, and these are set out in the Board Charter.

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

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

- Audit and Risk Committee;
- Remuneration and Human Resources Committee;
- Governance, Social and Ethics Committee; (ad hoc Committee)
- Finance Committee;
- National Academic and Pathology Committee;
- Research and Innovation Committee; and
- Executive Committee.

The various committees of the Board each have formal terms of reference embodied in a charter, which further defines the mandates, roles and responsibilities of each committee. The charters are reviewed and updated as needed.

The NHLS Board is governed by the NHLS Act 2000 (Act No 37 of 2000) and the NHLS Rules made in terms of the Act ***(supra)***. The Board complies with the PFMA and King IV principles of good governance.

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

A 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 other times as deemed necessary. The Board holds annual workshops to review the strategy and conduct an annual risk assessment. During the past 12 months, the Board convened fifteen (15) times (including special meetings). The NHLS Board is required to hold at least four meetings per 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. At each meeting, members were allowed to declare any personal conflict of interest to be recused from the deliberation of the matter in which they were involved. The table below and its accompanying legend illustrate the meeting attendance of Board members for the financial year: The table on page 132 and its accompanying legend illustrate the meeting attendance of Board members for the 2021/22 financial year:

Table 5: Board and Committees Attendance 01 April 2021 – 31 March 2022

Name	Meeting Dates															
	08/04/2021	26/05/2021	27/05/2021	28/07/2021	05/08/2021	20/10/2021	27/10/2021	10/11/2021	23/11/2021	24/11/2021	21/12/2021	19/01/2022	20/01/2022	23/02/2022	24/02/2022	TOTAL
Prof Eric Buch **(Board Chairperson)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
Prof Jeffrey Mphahlele **(Board Vice-Chairperson)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
Prof Thanyani Mariba **(Member)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
Ms Sphiwe Mayinga **(Member)**	✓	A	✓	✓	A	A	A	✓	✓	A	✓	n/m	n/m	n/m	n/m	6
Dr Balekile Mzangwa **(Member)**	✓	✓	✓	✓	✓	✓	A	✓	✓	A	✓	A	A	A	A	9
Mr Michael Sachs **(Member)**	✓	✓	A	✓	✓	A	✓	✓	✓	✓	✓	A	✓	A	A	10
Dr Gerhard Goosen **(Member)**	✓	✓	✓	✓	✓	✓	✓	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	7
Mr Koena Nkoko **(Member)**	✓	✓	✓	n/m	n/m	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	12
Prof Mary Ross **(Member)**	✓	✓	✓	✓	✓	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	5
Prof Tivani Mashamba-Thompson **(Member)**	n/m	n/m	n/m	n/m	n/m	n/m	n/m	✓	A	✓	✓	✓	✓	✓	✓	7
Prof Mpho Kgomo **(Member)**	A	A	A	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	A	✓	10
Dr Lesley Bamford **(Member)**	✓	✓	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	15
Dr Naledzani Ramalivhana **(Member)**	✓	✓	✓	✓	✓	✓	A	A	A	A	✓	A	A	✓	A	8
Dr Siseko Martin **(Member)**	✓	✓	✓	✓	A	A	✓	✓	✓	A	✓	✓	✓	✓	✓	12
Mr Jonathan Mallett **(Member)**	A	✓	✓	✓	✓	✓	✓	✓	A	A	A	✓	✓	A	A	2
Mrs Nicolene van der Westhuizen **(Member)**	✓	n/m	n/m	n/m	n/m	n/m	n/m	n/m	✓	✓	✓	✓	✓	✓	✓	5
Mr Nick Buick **(Member)**	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	A	✓	A	✓	✓	✓	A	4
Mrs Penelope Msimango **(Member)**	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	A	A	✓	A	✓	A	✓	3
Dr Mahlane Phalane **(Member)**	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	✓	✓	✓	A	A	✓	✓	5
Dr Kamy Chetty **(CEO)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
Total number of meetings	**15**															

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 National Health Laboratory Service Act 37 of 2000 to provide quality, affordable and sustainable health laboratories and related public health services.

The NHLS is the main provider of clinical support services to the national, provincial, and local health departments through its countrywide network of quality-assured diagnostic laboratories. The NHLS also supports communicable disease surveillance, occupational health and cancer and thus strives to align its strategy with both the DoH priorities and the National and Regional Burden of Disease.

The NHLS is managed according to the provisions of the National Health Laboratory Service Act 37 of 2000, as well as the NHLS Rules, gazetted in July 2007, and the Public Finance Management Act No. 1 of 1999. 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 areas (Limpopo and Mpumalanga, KwaZulu-Natal, Eastern Cape, Western and Northern Cape, Free State and North West, Gauteng) and two Institutes (NICD [which also manages the NCR and NIOH). Each area is headed by a Business Area Manager who reports directly to the Chief Operations Officer. The creation of six regions is intended to ensure that NHLS plans, agrees on budgets, and monitors laboratory services jointly with provincial health partners, with the intention of laboratory services being recognised and accepted as part of the public health delivery system. POCT is increasingly being used to speed up diagnosis within health facilities. NHLS recognises the value that POCT plays.

The NHLS delivers services throughout the public sector from the PHC level to tertiary or quaternary hospitals. The level of complexity and sophistication of services increases from peripheral laboratories to 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 Western Cape Provinces, 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 DoH 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 is a wholly-owned subsidiary of the NHLS and provides the following services:

1. SAVP manufactures biologicals, namely, antivenom, which include the following:

    i) Polyvalent antivenom
    ii) Echis antivenom
    iii) Boomslang antivenom
    iv) Spider antivenom
    v) Scorpion antivenom

2. Safety testing for pharmaceutical companies;

3. Research on routine products authorised via the animal ethics committee involving animals;

4. Preparation of horse and sheep serum;

5. Preparation and sampling of horse blood

GOVERNANCE,COMMITMENTS AND STAKEHOLDER ENGAGEMENT

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 economical, efficient, 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 concerning 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.

Legislative and Governance framework

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

- NHLS Act No.37 of 2000;
- General rules made in terms of S27 of the National Health Laboratory Service Act;
- National Health Act No. 61 of 2003;
- Protocol on Good Corporate Governance in the Public Sector,
- Public Finance Management Act No. 1 of 1999 (as amended);
- Treasury Regulations issued in terms of PFMA, 1999;
- Preferential Procurement Framework Act No. 5 of 2000;
- Relevant legislation applicable to the Health Sector;
- King IV Code on Good Corporate Governance; and
- 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 PFMA.

The Board is scheduled to meet every quarter. It is responsible for providing strategic direction and leadership, ensuring good corporate governance and ethics, determining policies, agreeing on performance criteria and delegating the detailed planning and implementation of policies to the EXCO.

The Board should be comprised of twenty-two (22) members, including the CEO, Chairperson, and Vice-Chairperson of the Board (twenty-one 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 approach is followed for delegation, reporting and accountability, including reliance on various Board committees. The chairperson guides and monitors the input and contributions of the Board members. The Board has unlimited access to professional advice on matters concerning the affairs of the economic entity at the entity's expense. The Board has approved a Code of Corporate Practice and Conduct, which includes the terms of reference that guide the Board members in discharging their duties and responsibilities.

The Board evaluates its effectiveness annually and formulates plans to mitigate any shortcomings identified by the evaluation process.

The Chairperson and Chief Executive Officer

The Chairperson is a non-executive and independent director (as recommended by good corporate governance practices). The chairperson can be invited to attend meetings of the board committees. The chairperson is a standing member of all the board committees. 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 Remuneration and Human Resources Committee (RHRC) is a committee of the Board that 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 has met on seven (7) separate occasions during the financial year. A joint Remuneration and Human Resources Committee and Finance Committee meeting was convened on 10 September 2021 to consider the financial position of the NHLS in response to the union's demands for an annual salary increase and a change in benefits.

Attendance at the Remuneration and Human Resources Committee ("RHRC") for the year 1 April 2021 to 31 March 2022:

Table 6: Meeting attendance Remuneration and Human Resources Committee members

Name	Meeting Dates							
	28/04/2021	14/07/2021	26/07/2021	23/09/2021	14/10/2021	15/02/2022	06/04/2022	TOTAL
Ms Sphiwe Mayinga **(Chairperson)**	✓	A	✓	✓	✓	n/m	n/m	4
Dr Balekile Mzangwa **(Vice-Chairperson)**	✓	✓	✓	✓	A	✓	✓	5
Mr Jonathan Mallett **(Vice-Chairperson)**	n/m	n/m	n/m	n/m	n/m	A	A	0
Dr Gerhard Goosen **(Member)**	✓	✓	✓	✓	A	n/m	n/m	4
Dr Lesley Bamford **(Member)**	A	✓	A	✓	✓	✓	✓	4
Mr Koena Nkoko **(Member)**	A	✓	✓	✓	✓	✓	✓	5
Dr Kamy Chetty **(CEO)**	✓	✓	✓	✓	✓	✓	✓	6
Total number of meetings	**7**							

LEGEND:

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

THE FINANCE COMMITTEE

The Finance Committee (FinCom) 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 the economic entity's sources and uses of funds.

FinCom has met on six (6) separate occasions during the financial year in terms of good corporate governance practices. During the period under review, two (2) special meetings were convened to consider procurement and finance submissions, which required urgent attention and Board approval.

Attendance at the **Finance Committee** ("FinCom") for the year 1 April 2021 to 31 March 2022:

Table 7: Meeting attendance Finance Committee members

Meeting Dates							
Name	**24/05/2021**	**27/05/2021**	**27/07/2021**	**13/10/2021**	**26/10/2021**	**10/02/2022**	**TOTAL**
Dr Gerhard Goosen **(Vice-Chairperson)**	✓	✓	✓	✓	✓	n/m	5
Mr Michael Sachs **(Chairperson)**	✓	A	✓	✓	✓	✓	5
Dr Balekile Mzangwa **(Member)**	A	A	✓	A	✓	✓	3
Dr Naledzani Ramalivhana **(Member)**	✓	✓	A	✓	A	✓	4
Mr Nick Buick **(Member)**	n/m	n/m	n/m	n/m	n/m	✓	1
Mrs Penelope Msimango **(Member)**	n/m	n/m	n/m	n/m	n/m	✓	1
Dr Mahlane Phalane **(Member)**	n/m	n/m	n/m	n/m	n/m	✓	1
Dr Kamy Chetty **(CEO)**	✓	n/m	n/m	✓	n/m	✓	3
Total number of meetings	**6**						

LEGEND:

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

THE AUDIT AND RISK COMMITTEE

In keeping with Treasury Regulation 27 of the PFMA, the Board appointed an Audit and Risk Committee to assist in discharging 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.

During the period under review, the Committee met three (3) times.

Table 8: Meeting attendance Audit and Risk committee members

	Meeting Dates			
Name	**24/05/2021**	**12/01/2022**	**01/03/2022**	**TOTAL**
Mr Michael Sachs **(Chairperson)**	✓	n/m	n/m	1
Mr Koena Nkoko **(Member/Chairperson)**	✓	✓	✓	3
Mr Nick Buick **(Vice-Chairperson)**	n/m	✓	✓	2
Dr Naledzani Ramalivhana **(Member)**	✓	✓	A	2
Mr Jonathan Mallett **(Member)**	✓	A	A	1
Ms Sphiwe Mayinga **(Member)**	✓	✓	n/m	2
Mr Goolam Manack **(Independent Member)**	✓	✓	✓	3
Dr Kamy Chetty **(CEO)**	✓	✓	✓	3
Total number of meetings	**3**			

LEGEND:

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

GOVERNANCE AND SOCIAL ETHICS COMMITTEE

The Committee was established to assist the Board with the oversight of corporate governance and social and ethical matters and to ensure 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 with respect to governance, social and ethics, and sustainable development-related matters, which inter alia, include the following:

(a) Safety;
(b) Health and wellness, including occupational hygiene;
(c) Environmental management;
(d) Climate change;
(e) Ethics management;
(f) Corporate social investment;
(g) Mine community development
(h) Stakeholder engagement; and
(i) The protection of company assets.

The Committee shall:

(a) Review and approve the policy, strategy, and structure to manage governance and social and ethical issues in the organisation.

(b) 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:

  i) The 10 principles set out in the United Nations Global Compact Principles
  ii) The OECD recommendations regarding corruption;
  iii) The Employment Equity Act;
  iv) The Broad-Based Black Economic Empowerment Act;

(c) 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 the communities in which its activities are predominantly conducted or within which its services are predominantly marketed, and record of sponsorship, donations and charitable giving;

(d) 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 its services.

(e) Oversee the monitoring, assessment and measurement of the organisation's stakeholder relationships, including its advertising, public relations and compliance with consumer protection laws to ensure that the organisation adheres to its values.

(f) Oversee the monitoring of the organisation's labour and employment, including its standing in terms of the International Labour Organization Protocol on decent work and working conditions, the organisation's employment relationships, and its contribution towards the educational development of its employees.

(g) Review the adequacy and effectiveness of the organisation's engagement and interaction with its stakeholders.

(h) Consider substantive national and international regulatory developments as well as practice in the fields of social and ethics management.

(i) Review and approve the policy and strategy of the organisation's programme of corporate social investment.

(j) 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.

(k) Monitor that management develops and implements programmes, guidelines and practices congruent with its social and ethics policies.

(l) 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.

(m) 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.

(n) 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 (7) 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. The attendance of the Governance and Social Ethics Committee (GSEC) for the period under review was as follows:

During the period under review, the Committee met four (4) times.

Table 9: Meeting attendance Governance and Social Ethics Committee members

Meeting Dates					
Name	22/09/2021	18/11/2021	17/12/2021	17/02/2022	TOTAL
Prof Eric Buch **(Board Chairperson)**	✓	✓	✓	✓	4
Prof Jeffrey Mphahlele **(Board Vice-Chairperson and Chair: RIC)**	A	A	✓	✓	2
Prof Thanyani Mariba **(Chair: NAPC)**	✓	✓	✓	✓	4
Ms Sphiwe Mayinga **(Chair: RHRC)**	✓	A	A	✓	2
Dr Balekile Mzangwa **(Chair: RHRC)**	n/m	n/m	✓	✓	2
Mr Michael Sachs **(Chair: FINCOM)**	✓	✓	A	✓	3
Dr Gerhard Goosen **(Vice-Chair: FINCOM)**	✓	n/m	n/m	✓	2
Mr Koena Nkoko **(Chair: ARC)**	n/m	n/m	A	✓	1
Dr Kamy Chetty **(CEO)**	A	✓	✓	✓	3
Total number of meetings	**4**				

LEGEND:

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

THE NATIONAL ACADEMIC AND PATHOLOGY COMMITTEE

The committee's function is to facilitate the formulation of policy concerning the following:

(a) the conduct of basic research in association or partnership with any tertiary educational institution;

(b) cooperation with individuals and institutions undertaking basic research in the Republic and in other countries through the exchange of scientific knowledge and the provision of access to the Service's resources and specimens;

(c) participation in joint research operations with state departments, universities, universities of technologies, colleges, museums, scientific institutions and other persons;

(d) cooperation with educational authorities and scientific or technical societies or industrial institutions representing employers and employees, respectively, to promote the instruction and training of pathologists, technologists, technicians, scientists, researchers, technical experts and other supporting personnel in universities, UoTs, and colleges; and

(e) any other matter as may be referred to the committee from time to time by the Board.

In performing some of its duties, the committee shall monitor and manage the agreements entered into between the service and each tertiary education institution, including the following:

(a) the development of policies and guidelines to determine the numbers of registrars for each discipline and the distribution of the registrar posts between the laboratories associated with each university health science faculty;

(b) the development of policies and guidelines to determine the numbers of technologist training posts for each discipline and the distribution of the posts between the laboratories identified for this purpose;

(c) proposing guidelines relating to part-time, honorary and guest appointment of employees of the service by tertiary education institutions;

(d)) monitor the guidelines for consultant appointments of personnel of tertiary education institutions in the service as determined by the agreement between the service and the universities;

(e) ensuring that the process of continuing professional development programmes provided by tertiary education institutions in the Service is used by Service employees to comply with Career Programme Development requirements;

(f) f) reviewing and managing arrangements for research being undertaken by tertiary education institutions in the laboratories of the service;

(g) advising executive management on matters relating to indemnity for employees of the service or a tertiary education institution working between the facilities of both partners;

(h) advising the executive management committee on matters relating to the discipline of personnel of the Service or a tertiary education institution working between the facilities of both partners;

(i) advising the executive management committee on financial matters, such as subsidies, bursaries and payment for academic-related services;

(j) monitoring, evaluating and managing service level agreements and performance measures;

(k) advising, monitoring and evaluating the resolution of disputes if they should arise;

(l) ensuring the integrity of the process of managing the partnerships;

(m) ensuring that professional ethics are adhered to; and

(n) ensuring that the Service complies with the requirements of the Health Professionals Council with respect to registration requirements, ethics and conduct.

The National Academic and Pathology Committee (NAPC), met on four separate occasions during the financial year. The attendance schedule is as follows:

Table 10: Meeting attendance National Academic and Pathology Committee members

Meeting dates					
Name	**20/05/2021**	**05/08/2021**	**28/10/2021**	**09/02/2022**	**TOTAL**
Prof Thanyani Mariba **(Chairperson)**	✓	✓	✓	✓	4
Prof Jeffrey Mphahlele **(Chairperson subcomm1)**	A	✓	✓	✓	3
Prof Mary Ross **(Member)**	✓	✓	n/m	n/m	2
Prof Mpho Kgomo **(Member)**	✓	✓	A	A	2
Mr Jonathan Mallett **(Member)**	✓	✓	A	A	2
Prof Tivani Mashamba-Thompson **(Member)**	n/m	n/m	n/m	✓	1
Mrs Nicolene van der Westhuizen **(Member)**	n/m	n/m	n/m	✓	1
Dr Kamy Chetty **(CEO)**	✓	✓	✓	✓	4
Total number of meetings	**4**				

LEGEND:

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

RESEARCH AND INNOVATION COMMITTEE

The committee has been established as a vehicle for ensuring that the NHLS research mandate receives attention at the 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 Research and Innovation Committee is to advise the NHLS Board and the NAPC on research policies, strategies, initiatives and innovations 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 NDoH 10-point plan and the National Health Research Committee (NHRC).

The Research and Innovation Committee ("RIC") met four (4) times for the period 1 April 2021 to 31 March 2022, and the attendance was as follows:

Table 11: Meeting attendance Research and Innovation Committee members

Meeting dates					
Name	**19/05/2021**	**04/08/2021**	**27/10/2021**	**18/02/2022**	**TOTAL**
Prof Mary Ross **(Chairperson)**	✓	✓	n/m	n/m	2
Prof Jeffrey Mphahlele **(Chairperson)**	n/m	n/m	n/m	✓	1
Prof Tivani Mashamba-Thompson **(Vice-Chairperson)**	n/m	n/m	n/m	A	0
Prof Thanyani Mariba **(Member)**	✓	✓	✓	n/m	3
Prof Mpho Kgomo **(Member)**	✓	A	A	n/m	1
Dr Naledzani Ramalivhana **(Member)**	✓	✓	A	A	2
Dr Siseko Martin **(Member)**	✓	✓	✓	✓	4
Dr Kamy Chetty **(CEO)**	✓	✓	✓	A	3
Total number of meetings	**4**				

LEGEND:

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

THE EXECUTIVE MANAGEMENT COMMITTEE

In terms of the NHLS Act, the Accounting Authority has appointed an Executive Management Committee (EXCO) that consists of the following:

(a) the CEO, who acts as chairperson; and

(b) Executive Managers within the NHLS and its operational units.

The EXCO is responsible for the management of the NHLS in accordance with the policy of the NHLS and assists with the performance of the Accounting Authority's functions and the exercise of its powers.

The Executive Committee met six (6) times during the period under review, and the attendance is as follows:

Table 12: Meeting attendance Executive Committee members

	Meeting dates						
Name	**13/04/2021**	**11/05/2021**	**08/06/2021**	**06/07/2021**	**06/09/2021**	**04/10/2021**	**TOTAL**
Dr Kamy Chetty (Chairperson)	✓	✓	✓	✓	✓	✓	6
Mr Jonas Shai (Acting CFO)	✓	✓	✓	✓	✓	✓	6
Mr Sibongiseni Hlongwane (CIO)	✓	✓	✓	✓	✓	✓	6
Prof Koleka Mlisana (AARQA Executive)	✓	A	✓	✓	✓	A	4
Prof Adrian Puren (Interim Director NICD)	✓	✓	A	✓	✓	✓	5
Dr Spo Kgalamono (NIOH Director)	✓	✓	A	✓	✓	✓	5
Ms Makgopelo Mkhwanazi (HR Executive)	n/m	n/m	✓	✓	✓	✓	4
Mr Jone Mofokeng (Acting HR Executive)	✓	✓	n/m	n/m	n/m	n/m	2
Advocate Mpho Mphelo (Company Secretary)	✓	✓	✓	✓	✓	✓	6
Total number of meetings	**6**						

LEGEND:

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

THE OPERATIONAL COMMITTEE ("OPCO")

The Operational Committee was established by the Accounting Officer to assist the Executive Committee in discharging its duties and ensure that all strategic decisions taken are operationalised and monitored. The Committee comprises members of the Executive Committees, regional managers from six regions (namely, Gauteng, Eastern Cape, KwaZulu-Natal, Limpopo - Mpumalanga, Western – Northern Cape, and North West – Free State), and all heads of units within the NHLS.

The Committee met eighteen (18) times during the year under review. The attendance is as follows:

Table 13: Meeting attendance Operational Committee members

Name	Meeting dates																		
	12/04/2021	10/05/2021	17/05/2021	07/06/2021	28/06/2021	29/06/2021	30/06/2021	05/07/2021	15/07/2021	19/07/2021	16/08/2021	13/09/2021	11/10/2021	08/11/2021	06/12/2021	10/01/2022	07/02/2022	07/03/2022	TOTAL
Dr Kamy Chetty **(Chairperson)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Mr Jonas Shai **(Acting CFO)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Mr Sibongiseni Hlongwane **(CIO)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	**17**
Prof Koleka Mlisana **(AARQA Executive)**	✓	A	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	**15**
Prof Adrian Puren **(Interim Director NICD)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Dr Spo Kgalamono **(NIOH Director)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Ms Makgopelo Mkhwanazi **(HR Executive)**	n/m	n/m	n/m	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**15**
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	**3**
Advocate Mpho Mphelo **(Company Secretary)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	**17**
Prof Wendy Stevens **(NPP Executive)**	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**17**
Prof Elizabeth Mayne **(EC Chair)**	✓	✓	A	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	✓	**16**
Mr Nkosinathi Khumalo **(Head: Risk & Internal Audit)**	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**17**
Ms Violet Gabashane **(SM: M&E)**	✓	✓	✓	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**17**
Mr Mzimasi Gcukumana **(SM: Communications)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Mr Jone Mofokeng **(Area Manager: FS & NW)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Ms Tabita Makula **(Area Manager: EC)**	✓	✓	A	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**16**
Mr Sibulele Bandezi **(Area Manager: KZN)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Mr Jacob Lebudi **(Area Manager: Limp & MP)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	A	✓	✓	**17**
Ms Nasima Mohamed **(Area Manager: NC & WC)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**18**
Mr Bahule Motlonye **(Area Manager: GP)**	✓	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	A	✓	A	✓	✓	**15**
Total number of meetings	**18**																		

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 shareholders 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 guides both the executive and 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:

- Providing induction of new Board members;
- Providing Board members, collectively and individually, with guidance in 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;
- Recording of Board and Committees proceedings;

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

AUDIT AND RISK COMMITTEE REPORT

The committee is pleased to present its report for the financial year that ended on 31 March 2022.

Audit and Risk Committee responsibilities

The committee reports that appropriate formal terms of reference were 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 the Annual Financial Statements (AFS). The committee 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's assessment of internal control systems is depicted in the table below and is based on eight (8) business processes.

Table 14: The effectiveness of internal controls

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	😊

Heatmap legend:	Satisfactory 😊	Weak 😐	Unsatisfactory ☹

Management has committed to improve the control environment where there are ineffective internal control systems. This will be monitored at every Audit and Risk Committee meeting.

The committee also notes with concern that management did not resolve all findings that were reported by external auditors in the previous financial year. Internal Audit Function will perform follow-up audits to establish whether corrective actions have been implemented by management to address external audit findings and 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 function needs to be adequately capacitated and resourced in order to fulfil its responsibilities. The committee is satisfied that 84% of the internal audit reviews included in the approved Annual Internal Audit Plan were completed and only 16% was deferred to 2022-2023 financial year. The committee reviewed the internal audit reports and indicated the need for management to address reported findings. The reports reviewed include, amongst others:

- Property, plant and equipment;
- Accounts receivable and revenue;
- Procurement and account payable;
- Payroll and human resources;
- An audit of performance information;
- Laboratory reviews;
- Information Technology General and Application controls reviews;
- Tender Compliance reviews; and
- Follow-up on reported audit findings.

Risk management

The responsibility for risk management resides with management, with the Board playing an oversight role. Risk management processes are embedded throughout the organisation, from Board level to all employees within the organisation. The NHLS conducts risk assessment workshops to ensure that significant risks are identified and managed on an ongoing basis.

The NHLS has a dedicated Risk Management and Internal Audit Department to coordinate the implementation of risk management strategy, as approved by the Board. The Board continues to discharge this responsibility through the Audit and Risk Committee. The strategic and operational risk assessment workshops were facilitated during the financial year. The progress on implementation of the risk mitigation actions plan was submitted during quarterly meetings. This enabled the committee to monitor the effectiveness of these actions in mitigating the identified risks. The committee is satisfied with management action plan to mitigate identified risks..

Fraud and corruption

Anonymous tip-off platforms for reporting fraud, corruption, and unethical behaviour were operational during the financial year. These platforms are administered by an independent service provider. The reported allegations were investigated and final investigation reports with findings, conclusions, and recommendations were presented at committee meetings. The committee obtained commitment from management that recommendations from the investigation reports were being implemented.

Competency of the finance department

The committee acknowledges that the Finance department has inadequate resources and competency gaps. Management has committed to correct 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 Annual Financial Statements;
- Management report from external auditors;
- Accounting policies and practices;
- Compliance with legal and regulatory provisions; and
- Significant adjustments to Group Annual Financial Statements.

The committee concurs with the external auditors' report and is of the opinion that the audited Group Annual Financial Statements should be accepted. Moreover, having had regard to NHLS's statutory and other responsibilities as well as all factors that may have an impact on the integrity of the financial statements, the committee accepted the application of a going concern premise and recommended that the NHLS board should approve the Group Annual Financial Statements.

Mr Koena Nkoko
Chairperson: Audit and Risk Committee

Date: 23 August 2022

PART D
HUMAN RESOURCES

Makgopelo Mkhwanazi
Executive Manager

EXECUTIVE SUMMARY

The NHLS aims to provide a balance between the employee headcount and the labour costs maintained within the allocated budget while adhering to market-based principles of fair and equitable remuneration.

The total employee costs as a percentage of the total expenditure have slightly increased from 36% to 38% due to the salary increases averaging 5% that were approved during the period under review. These dated back to two financial years.

The total headcount reported in Tables 1 and 2 and the figure reported in Table 4 are different based on the fact that the financial tables report on all employees, including those who were paid post-termination (this is leave and settlements), while Table 4 only reports on active headcount. In total, the headcount has been reduced by 2.8% due to fixed-term contracts that have ended.

Skills development has been primarily driven through the Workplace Skills Plan (WSP) process, with 92% implementation achieved, 245 employees attended PIVOTAL programmes with 74 attending ABET. The cost of training as a percentage of the total training cost is 0.85% at an average of R3000 per employee.

The total exits for the period under review recorded an increase of 3.9% compared to the previous reporting period. The major increases were noted, with resignations that have gone up by 1.8% and retirements that have gone up by 0.5% from the previous reporting period. Even though the number of labour-related cases has increased overall from the previous reporting period, the trends in terms of the sanctions issued are still aligned.

The main challenge in employment equity is the appointment of employees with disabilities, which still remains below the target of 2% by a visible margin. The status has not changed since the previous reporting period.

Table 1: Personnel Cost by programme/activity/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	12 764 965	4 783 603	37%	8 387	570 359

***Note that the above total expenditure figure is currently provisional, as the finance system has not closed yet for FY 2021/22*

Table 2: Personnel cost by salary band

Programme/activity/objective	Personnel Expenditure (R'000)	% of personnel exp. to total personnel cost	No. of employees	Average personnel cost per employee
Top Management	22 295	0,5%	8	2 786 931
Senior Management	102 675	2,1%	42	2 444 653
Professional Qualified	1 199 713	25,1%	916	1 309 731
Skilled	2 077 026	43,4%	3 222	644 639
Semi-skilled	1 137 056	23,8%	2 992	380 032
Unskilled	169 510	3,5%	798	212 418
Training - learnerships	75 327	1,6%	409	184 174
TOTAL	**4 783 603**	**100%**	**8 387**	**570 359**

Personnel expenditure as a generalisation showed an increase of 13.% (4 783 603) compared to the previous year (4 202 399). The semi-skilled occupational level has increased by 1% from 22.87% last year. It was followed by the unskilled level, with an increased percentage of 0.94% compared to 2.56% in the previous year. Skilled, training, and top management occupational levels showed slight increases of below 0.5%. Personnel expenditure for qualified professional levels decreased by 1,3% compared to the previous year's 26.24%. Senior management also showed a decrease in personnel expenditure of 0.41% compared to the previous year's 2.51%.

The headcount is as of the end of March 2022 and has generally shown a decrease of 2.8% (8387) compared to the previous year, which was 8632. The semi-skilled and skilled occupational levels showed the highest loss regarding the headcount.

The general increase in personnel expenditure can be attributed to the annual salary increase and adjustment of insourced employees to the minimum of their respective pay scales, which was brought forward by the Board decision. The majority of these insourced employees are at the unskilled and semi-skilled occupational levels. The decrease in headcount can be attributed to fixed-term contractors who were employed during the COVID-19 pandemic whose contracts came to an end resulting from decreased positive cases.

Table 3: 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)	4 680 729	40 073 461	0,000856129	6737	3000.00
PIVOTAL programmes for non-employees (higher education qualifications)	N/A	N/A	N/A	N/A	N/A
PIVOTAL programmes for non-employees participating in learnerships, on-the-job training and workplace experience	28 885 611	N/A	N/A	260	N/A

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

The NHLS continues to fulfil its mandate of promoting and prioritising skills development through the analysis of its employees' skills needs by implementing the WSP. Multiple learning programmes are offered through short learning programmes, in-service conferences and congresses, as well as 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 162% of the planned training target compared to the legislated target of 60%, 108% against the NHLS Annual Performance Plan of 90% and 92% against 100% on total performance.

- These figures are represented by 6737 training interventions attended by technical and non-technical employees against a planned target of 6947. The programmes for employees were both pivotal and non-pivotal including internal bursaries for formal academic qualifications, short learning programmes, workshops, seminars, on-the-job training and conferences for the 2021-2022 period.
- Out of 6737 total interventions, 245 employees attended pivotal programmes (certificates, diplomas, undergraduate and postgraduate degrees), and 74 attended the Adult Education and Training Programme.
- There are also **pivotal** programmes for **non-employees** participating in learnerships, on-the-job training and workplace experience. This includes a total number of 260 who pursued their career development by way of being placed on a professional development programme and platforms in which personnel were trained, including medical technology students, medical technician students, medical officer community service, medical scientists and experiential students.

The NHLS has met both statutory requirements (60% HWSETA target of the WSP) in this financial year and the NHLS Performance Plan (90% WSP APP target). For both online and face-to-face training, the organisation adapted and adopted innovative blended learning methodologies. As part of the COVID-19 pandemic response, the organisation moved 50% of its courses online.

Table 4: Employment and Vacancies

Programme/activity/ objective	2020/2021 No. of Employees	2021/2022 Approved Posts	2021/2022 No. of Employees	2021/2022 Vacancies	% of vacancies
Top Management	7	11	8	3	27,3%
Senior Management	50	51	42	9	17,6%
Professional Qualified	944	1 085	916	169	15,6%
Skilled	3 288	3 496	3 222	274	7,8%
Semi-skilled	3 142	3 263	2 992	271	8,3%
Unskilled	808	845	798	47	5,6%
Training - learnerships	393	410	409	1	0,2%
Total	**8 632**	**9 161**	**8 387**	**774**	**8,4%**

The above table reflects the total number of employees at the start and end of the reporting period, including vacancies. The staff headcount decreased by 2.92% from April 2021 to 31 March 2022 compared to the headcount at the closing period in March 2021.

Some of the fixed-term contracts that terminated and were not extended during this reporting period are to be attributed to the reduction in personnel headcount.

The above vacancy rate of 8.4% reflects budgeted vacant positions at the end of the reporting period, which may appear high because our national laboratories continue to prioritise recruiting core and laboratory support employees.

A total of 743 vacancies were recorded as existing vacant positions, while thirty-one (31) were reported as newly created vacancies that are grant-funded.

The demand for health professionals and laboratory staff has remained on an upwards curve during the reporting period. As the public became aware of the benefits of vaccination and got vaccinated, the infection rates decreased, thus reducing the attraction of laboratory staff as well, compared to the bulk recruitment we experienced at the beginning of the COVID-19 pandemic. The nature and headcount of these fixed-term contracts change as the project moves to its full life cycle, thus explaining the reduction of staff in the semi-skilled category, as this is the category where the majority of the COVID-19 laboratory staff are reported.

Table 5: Employment changes

Programme/activity/objective	Employment at the beginning of the period	Appointments	Terminations	Employment at the end of the period
Top Management	7	1	1	8
Senior Management	50	0	7	42
Professional Qualified	944	77	257	916
Skilled	3 288	64	114	3 222
Semi-skilled	3 142	157	298	2 992
Unskilled	808	34	39	798
Training - learnerships	393	338	200	409
Total	**8 632**	**671**	**916**	**8 387**

The headcount of 8387 on 31 March 2022 shows that NHLS staff establishment has decreased by 2.9% compared to the 8632 headcounts at the closing of the past financial year. As shown in **Table 35** above, appointments in all occupational categories decreased compared to last year except for student interns/learnerships, which increased by 4.1%.

While we have lately noted a lower rate of COVID-19-related infections, this could be due to the introduction of vaccination, as well as the awareness and/or adherence to COVID-19 guidelines such as wearing masks and sanitising, among other things.

It is, however, imperative for NHLS Top Management to review and/or establish whether all or perhaps some of the laboratory support staff ***(fixed-term contracts)*** recruited for the COVID-19 pandemic could be permanently retained and/or absorbed. The decision and/or consideration of retaining this cohort of laboratory staff will help to strengthen the quality of service that NHLS laboratories offer to the South African public as well as improve the turn-around-time of the laboratory results that NHLS performs.

It is worth noting that the headcount of the fixed-term contracts on 31 March 2022 was 621, of which the majority of these contracts are pre-analytical and laboratory staff recruited for the COVID-19 pandemic. During this reporting period, there were 6919 permanent staff members, and there were 457 fixed-term contracts over 18 months, with a total of 262 registrars included in the contracts over 18 months.

Table 6: Reasons for leaving

Reason	Total Count	% of total no. of staff leaving
Death	28	0,3%
Resignation	376	4,5%
Dismissal	44	0,5%
Retirement	113	1,3%
Ill health	8	0,1%
Expiry of contract	343	4,1%
Other	4	0,05%
TOTAL	**916**	**10,9%**

As reflected in the above table, NHLS recorded a turnover of 4.5% as a percentage of the staff headcount on 31 March 2022. This turnover rate of 4.5% was based on voluntary resignations for all contract types on 31 March 2022.

The turnover rate based on only permanent headcount and fixed-term contracts above 18 months was 3.9% during the FY2021/22. In this reporting period, we sadly recorded a 33% increase in employees who left the organisation due to ill health compared to FY2020/21. On a positive note, the FY2021/22 termination report revealed a reduction in the number of deceased staff by 25% compared to the previous year. Unfortunately, that cannot be said regarding the dismissal of staff in the NHLS, as this has doubled compared to the past financial year.

The largest number of staff categories that left the organisation were laboratory clerks. Thirteen percent of the laboratory clerks who left retired, 16% were fired, and 8% died, while 33% of those who resigned cited personal reasons and better job offers as their reasons for leaving. Forty percent of the laboratory clerks' exits were due to the expiration of contracts, and it should be noted that some of the contracts are renewed if the services are still required and the budget is available. The total number of staff members who retired during this reporting period was 116. However, three of them were rehired as post-retirees, as they hold the pathology-scarce skills that are core to our business.

A wider understanding of the demographics of all the job categories needs to be established to enable the implementation of an effective talent management framework, skills transfer and succession planning. *(Refer to Tables 8 a and b below.)*

Table 7: Labour Relations - Misconduct and disciplinary action

Nature of disciplinary Action	Number
Verbal warning	22
Written warning	24
Final written warning	45
Dismissal	43
Not guilty	16
Pending	29
TOTAL	**183**
Resigned	3
End of contract	1

Formal disciplinary action was taken against staff members, accounting for 2.1 percent of the NHLS' total staff complement. Only 0.5% of staff members were issued the ultimate sanctions, which terminated their contracts of employment with the NHLS. Although the numbers have increased, these figures depict a generally disciplined workforce. As required by law, some of the cases had to be reported to law enforcement authorities for further action.

Table 8: 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	4	1	0	0	0	0	1
Senior Management	8	13	0	2	2	2	6	7
Professional Qualified	116	225	29	46	41	42	86	87
Skilled	698	829	67	104	53	54	49	113
Semi-skilled	738	865	70	99	33	39	10	76
Unskilled	294	312	11	13	0	3	1	7
TOTAL	**1 856**	**2248**	**178**	**264**	**129**	**140**	**152**	**291**

The DEL provides statistics on the demographics of the economically active population according to race and gender. Underrepresentation of African males and Coloured males is recorded in senior management, and the professionally qualified levels effectively targeted groups for recruitment. All males are underrepresented at the skilled level.

The following reductions were noted when compared to the previous year: African males make up 3%; Coloured males make up 1.6%; Indian males make up 5.8% and White males make up 4.4%.

Table 9: 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	3	3	0	0	1	1	0	0
Senior Management	8	10	2	2	5	6	9	12
Professional Qualified	285	321	36	43	103	105	183	187
Skilled	1 601	1 613	165	169	165	170	212	218
Semi-skilled	698	1 481	67	194	53	46	49	73
Unskilled	450	453	22	25	1	3	0	5
TOTAL	**3 045**	**3 881**	**292**	**433**	**328**	**331**	**453**	**495**

African females and Coloured females are underrepresented (according to the economically active population demographics) in senior management and the professionally qualified level, hence remaining the main targeted groups for recruitment purposes. All female groups are overrepresented at the skilled level.

The following reductions were noted when compared to the previous year: African females = 21.4%; Coloured females = 31.4%; Indian females = 2% and White females = 9.4%.

Table 10: 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	0	2
Professional Qualified	0	1	0	1
Skilled	2	2	17	20
Semi-skilled	2	2	4	7
Unskilled	2	3	3	4
TOTAL	**6**	**9**	**24**	**34**

The representation of people with disabilities remains at 0.5% below the compliance target of 2%.

PART E

FINANCIAL INFORMATION

GENERAL INFORMATION

Country of incorporation and domicile	South Africa
Legal form of entity	PFMA Schedule 3A Entity
Nature of business and principal activities	Healthcare, research and training
Board members	Prof Eric Buch Prof Jeffrey Mphahlele Dr Kamy Chetty Dr Lesley Bamford Mr Nick Buick Prof Mpho Klass Kgomo Mr Jonathan Mallett Prof Thanyani Mariba Dr Siseko Martin Dr Balekile Mzangwa Mr Koena Joseph Nkoko Dr Naledzani Ramalivhana Mr Michael Sachs Prof Tivani Mashamba - Thompson Mrs Nicolene van der Westhuizen Ms Thandi Msimango Dr Mahlane Kenneth Phalane
Registered office	1 Modderfontein Road Rietfontein Sandringham Johannesburg 2000
Postal address	Private Bag X 8 Johannesburg 2131
Shareholder	National Department of Health
Bankers	First National Bank Ltd Nedbank Ltd Investec Ltd Rand Merchant Bank Ltd
Auditors	Nexia SAB&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 and Finance Management (PFMA) Act, no. 1 of 1999 Treasury regulations in terms of PFMA, 1999 The Companies Act, No, 71 of 2008 The National Health Act, No. 61 of 2003
Published	22 August 2022

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ACTING CHIEF FINANCIAL OFFICER'S REPORT

Pumeza Mayekiso
Acting Chief Financial Officer

Introduction

The 2021/22 financial year was characterised by the National Health Laboratory Service (NHLS)'s continued aim to support the fight against the COVID-19 pandemic. The NHLS continued to gain traction towards fully re-establishing its services rendered at pre-COVID-19 pandemic levels. To this end, the NHLS has stabilised its finances and maintained a strong financial position for the financial year ended 31 March 2022.

The NHLS has maintained an unqualified audit opinion, with findings, for the last four consecutive financial years.

Overview: Statement of Financial Performance

The NHLS generated a surplus of R76.4 million for the 2021/22 financial year, which is an increase from R65.4 million in the previous financial year. The organisation's revenue also grew from R10.5 billion to R12.2 billion. Revenue from rendering services accounts for 95% (R11.6 billion) of total revenue. Revenue on COVID-19 testing amounted to R2.4 billion, with over 5 million tests conducted.

The cost of sales, which includes direct labour and materials, decreased from R10.5 billion to R10.1 billion.

This equates to a 3% decrease. Labour costs constituted 43% of the cost of sales. Direct material costs constituted 54% of the cost of sales, compared to 63% in the previous financial year.

Overview: Statement of Financial Position

The NHLS total assets increased from a restated R7.4 billion in the prior year to R7.8 billion in the current year. Inventory has been reduced in line with the use of the COVID-19 inventory that has been procured by the NHLS. Receivables increased in line with revenue. Cash and cash equivalents increased from R3 billion to R3.5 billion in the current year. Current liabilities increased from R2 billion to R2.2 billion (an 11% increase) due to an increase in payables from exchange transactions. The NHLS has maintained strong financial viability and has consolidated and enhanced its cash reserves.

Cash flow

A net cash inflow of R531 million was received in the 2021/22 financial year. This is mainly attributable to a net cash inflow from operating activities of R875 million. Suppliers were paid R7.1 billion during the year, compared with R7.7 billion in the prior year. Employee costs amounted to R4.7 billion compared to R4.2 billion in the prior year. A net cash outflow from investing activities of R319 million was also incurred. This is mainly attributable to the purchase of laboratory equipment.

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. The NHLS management has 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 enhanced cash and cash equivalents at levels that ensure continuity of service. Debtors' collection remains at an acceptable level. 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 especially on 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 PFMA. During the financial year under review, the entity did not borrow funds to finance its operations.

Lastly, it is imperative to express appreciation to the Board for the strategic direction and the leadership of the CEO that have proven to be invaluable in carrying out the entity's mandate.

Ms Pumeza Mayekiso
Acting Chief Financial Officer

Date: 22 August 2022

ACCOUNTING AUTHORITY'S RESPONSIBILITIES AND APPROVAL

The Accounting Authority is required by the Public Finance Management Act No 1 of 1999 (as amended) to maintain adequate accounting records and is responsible for the content and integrity of the audited Annual Financial Statements and related financial information included in this report. It is the responsibility of the Accounting Authority to ensure that the audited 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 that ended. The external auditors were engaged to express an independent opinion on the audited annual Financial Statements and were given unrestricted access to all financial records and related data.

The group audited Annual Financial Statements have been prepared in accordance with the Standards of Generally Recognised Accounting Practice (GRAP) including any interpretations, guidelines and directives issued by the Accounting Standards Board.

The audited Annual Financial Statements are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The Accounting Authority acknowledges that it 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 throughout 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 light of this review and the current financial position, is satisfied that the economic entity has access to adequate resources to continue in operational existence for the foreseeable future.

The economic entity is wholly dependent on public healthcare providers for continued funding of operations. The audited Annual Financial Statements are prepared on the basis that the economic entity 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 169-242, which have been prepared on a going concern basis, were approved by the Accounting Authority on 22 August 2022 and were signed on its behalf by:

Dr Kamy Chetty
Chief Executive Officer

Prof Eric Buch
Chairperson: Accounting Authority

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 its subsidiary (the group) set out on pages 169-242, which comprise the consolidated and separate statement of financial position as at 31 March 2022, the consolidated and separate statement of financial performance, consolidated and separate statement of changes in net assets, consolidated and separate cash flow statement and consolidated and separate 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 consolidated and separate financial position of the group as at 31 March 2022, and its consolidated and separate financial performance and consolidated and separate 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 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 matters

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 39 to the financial statements, the corresponding figures for 31 March 2021 were restated as a result of an error in the financial statements of the group at, and for the year ended, 31 March 2022.

Material allowance for impairment

8. As disclosed in note 4 to the financial statements, material allowance for impairment of R4 790 169 000 was recorded against receivables from exchange transactions as a result of irrecoverable debt.

Irregular expenditure

9. As disclosed in note 38 to the financial statements, the group incurred irregular expenditure of R1 284 344 000 (2021: R778 639 000). 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 243-244 does not form part of the consolidated and separate 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 the Accounting Authority for the consolidated and separate financial statements

12. 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 2022:

Programme	Pages in the annual performance report
Programme 1 – Laboratory Service	35 – 37

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 matters

21. We draw attention to the matters below.

Achievement of planned targets

22. Refer to the annual performance report on pages 35 to 46 for information on the achievement of planned targets for the year and management's explanations provided for the under/ over achievement of targets.

Adjustment of material misstatements

23. We identified material misstatements in the annual performance report submitted for auditing. These material misstatements were in the reported performance information of programme 1: Laboratory service. As management subsequently corrected the misstatements, we did not raise any material findings on the usefulness and reliability of the reported performance information.

REPORT ON THE AUDIT OF COMPLIANCE WITH LEGISLATION

Introduction and scope

24. 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.

25. The material findings on compliance with specific matters in key legislation are as follows:

Annual financial statements

26. The financial statements submitted for auditing were not fully prepared in accordance with the prescribed financial reporting framework and supported by full and proper records, as required by section 55(1) (a) and (b) of the PFMA.

27. Material misstatements of non-current assets, current assets, liabilities, expenditure and disclosure items, identified by the auditors in the submitted financial statement, were corrected and the supporting records were provided subsequently, resulting in the financial statements receiving an unqualified audit opinion with findings.

Expenditure management

28. Effective and appropriate steps were not taken to prevent irregular expenditure, as required by section 51(1) (b)(ii) of the PFMA. The value as disclosed in note 38, is not complete as management was still in the process of quantifying the full extent of the irregular expenditure. 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

29. Some of the quotations and contracts were awarded to bidders who did not submit a declaration on whether they are employed by the state or connected to any person employed by the state, which is prescribed in order to comply with Treasury Regulation 16A8.3. Similar non-compliance was also reported in the prior year.

30. Some of the goods and services of a transaction value above R500 000 were procured without inviting competitive bids, as required by Treasury Regulation 16A6.1 and paragraph 3.4.1 of Practice Note 8 of 2007/2008.

31. Some of the persons in service of the entity who had a private or business interest in contracts awarded by the entity failed to disclose such interest, as required by Treasury Regulation 16A8.4.

OTHER INFORMATION

32. The Accounting Authority is responsible for the other information. The other information comprises the information included in the annual report. 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.

33. Our opinion on the financial statements and my 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.

34. 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.

35. We did not receive the other information prior to the date of this auditor's report. When we do receive and read this information, if we conclude that there is a material misstatement therein, we are required to communicate the matter to those charged with governance and request that the other information be corrected. If the other information is not corrected, we may have to retract this auditor's report and re- issue an amended report as appropriate. However, if it is corrected this will not be necessary.

INTERNAL CONTROL DEFICIENCIES

36. 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 basis for the opinion and the findings on compliance with legislation included in this report.

37. 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 consolidated and separate financial statements.

OTHER REPORTS

38. 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 consolidated and separate financial statements or our findings on the reported performance information or compliance with legislation.

39. The Special Investigating Unit is currently investigating allegations of 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.

40. The Special Investigating Unit concluded an investigation into allegations of impropriety in connection with the procurement of, or contracting for goods, works and services, including the construction, refurbishment, leasing, occupation and use of immovable property, during, or in respect of the National State of Disaster, at the request of the President of the Republic of South Africa (Proclamation No R23 of 2020), covering the period 23 July 2020 to 30 September 2021. The investigation was concluded on 10 December 2021 and resulted in criminal proceedings being undertaken against the implicated suppliers. The investigation resulted in a contingent asset being recognised in the financial statements of the group. The court proceedings were still in progress at the date of this auditor's report.

41. The Directorate for Priority Crime Investigation ("The Hawks") is currently investigating allegations of the possible procurement and contract management irregularities. These proceedings were still in progress at the date of this auditor's report.

42. An independent consultant investigated allegations of irregularities pertaining to purchase orders awarded to some companies relating to the COVID-19 emergency procurement events, at the request of the group. The investigations were concluded between 1 September 2021 to 8 March 2022 and the disciplinary proceedings resulted in dismissal and sanctions against several implicated employees.

AUDITOR TENURE

43. 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 three years.

Nexia SAB&T

Nexia SAB&T
N.C. Soopal
Director
Registered Auditor

Date: 23 August 2022

119 Witch Hazel Avenue
Highveld Technopark
Centurion
0146

ANNEXURE – AUDITOR'S RESPONSIBILITY FOR THE AUDIT

1. As part of an audit in accordance with the ISAs, we exercise professional judgement and maintain professional scepticism throughout our audit of the consolidated and separate financial statements, and the procedures performed on the reported performance information for selected programmes and on the group's compliance with respect to the selected subject matters.

Financial statements

2. In addition to our responsibility for the audit of the consolidated and separate financial statements as described in this auditor's report, we also:

   - identify and assess the risks of material misstatement of the consolidated and separate 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 our 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 group's internal control

   - evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors, which constitutes 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. We 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 National Health Laboratory Service and its subsidiary to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements about the material uncertainty or, if such disclosures are inadequate, to modify our opinion on the financial statements. Our conclusions are based on the information available to us at the date of this auditor's report. However, future events or conditions may cause the group 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 consolidated and separate financial statements represent the underlying transactions and events in a manner that achieves fair presentation

   - obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion

Communication with those charged with governance

3. We 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 we identify during our audit.

STATEMENT OF FINANCIAL POSITION AS AT 31 MARCH 2022

	Note(s)	Economic entity		Controlling entity	
		2022 R'000	2021 Restated* R'000	2022 R'000	2021 Restated* R'000
Assets					
Current Assets					
Inventories	3	837 463	1 120 828	829 729	1 115 882
Current tax receivable	31	425	-	-	-
Receivables from exchange transactions	4	1 944 597	1 565 190	1 943 985	1 562 540
Receivables from non-exchange transactions	5	34 867	282 236	34 867	282 236
VAT receivable		126	-	-	-
Cash and cash equivalents	6	3 483 308	2 952 072	3 472 883	2 942 959
		6 300 786	**5 920 326**	**6 281 464**	**5 903 617**
Non-Current Assets					
Sheep and Horses	8	66	50	-	-
Property, plant and equipment	7	1 478 997	1 452 189	1 477 273	1 450 281
Intangible assets	9	5 128	6 506	5 128	6 506
		1 484 191	**1 458 745**	**1 482 401**	**1 456 787**
Total Assets		**7 784 977**	**7 379 071**	**7 763 865**	**7 360 404**
Liabilities					
Current Liabilities					
Other financial liabilities	12	-	4 920	-	4 920
Current tax payable	31	-	2 026	-	-
Finance lease obligation	13	-	18 727	-	18 727
Payables from exchange transactions	14	1 474 199	1 144 725	1 468 289	1 143 686
VAT payable		-	108	-	-
Post retirement medical benefit plan	15	41 725	37 510	41 725	37 510
Unspent conditional grants and receipts	16	70 866	113 111	70 866	113 111
Provisions	17	638 068	674 754	638 068	674 754
		2 224 858	**1 995 881**	**2 218 948**	**1 992 708**
Non-Current Liabilities					
Finance lease obligation	13	-	102	-	102
Post retirement medical benefit plan	15	981 571	881 878	981 571	881 878
Deferred tax	18	1 287	389	-	-
		982 858	**882 369**	**981 571**	**881 980**
Total Liabilities		**3 207 716**	**2 878 250**	**3 200 519**	**2 874 688**
Net Assets		**4 577 261**	**4 500 821**	**4 563 346**	**4 485 716**
Reserves					
Revaluation reserve		654 919	654 919	654 919	654 919
Accumulated surplus		3 922 342	3 845 902	3 908 427	3 830 797
Total Net Assets		**4 577 261**	**4 500 821**	**4 563 346**	**4 485 716**

STATEMENT OF FINANCIAL PERFORMANCE

	Note(s)	Economic entity		Controlling entity	
		2022 R'000	2021 Restated* R'000	2022 R'000	2021 Restated* R'000
Revenue	19	12 237 665	10 537 490	12 223 971	10 511 848
Cost of sales	20	(10 117 395)	(10 450 491)	(10 099 073)	(10 427 869)
Gross surplus		**2 120 270**	**86 999**	**2 124 898**	**83 979**
Other income	21	400 773	1 051 680	400 773	1 051 680
Operating expenses	27	(2 639 024)	(1 232 840)	(2 640 449)	(1 228 904)
Operating deficit	22	**(117 981)**	**(94 161)**	**(114 778)**	**(93 245)**
Interest income	23	201 404	163 705	200 943	163 186
Fair value adjustments		1	15	-	-
Interest expense	24	(8 546)	(3 697)	(8 546)	(3 697)
Surplus before taxation		**74 878**	**65 862**	**77 619**	**66 244**
Taxation	25	1 553	(480)	-	-
Surplus for the year		**76 431**	**65 382**	**77 619**	**66 244**

STATEMENT OF CHANGES IN NET ASSETS

	Revaluation reserve '000	Accumulated surplus '000	Total net assets '000
Economic entity			
Balance at 01 April 2020	**654 919**	**3 780 520**	**4 435 439**
Changes in net assets			
Surplus for the year	-	65 382	65 382
Total changes	-	65 382	65 382
Opening balance as previously reported	654 919	3 834 848	4 489 767
Adjustments			
Correction of errors	-	11 063	11 063
Restated* Balance at 01 April 2021 as restated*	**654 919**	**3 845 911**	**4 500 830**
Changes in net assets Surplus for the year	-	76 431	76 431
Total changes	-	76 431	76 431
Balance at 31 March 2022	**654 919**	**3 922 342**	**4 577 261**
Controlling entity			
Balance at 01 April 2020	**654 919**	**3 764 553**	**4 419 472**
Changes in net assets			
Surplus for the year	-	66 244	66 244
Total changes	-	66 244	66 244
Opening balance as previously reported	654 919	3 819 745	4 474 664
Adjustments			
Correction of errors*	-	11 063	11 063
Restated* Balance at 01 April 2021 as restated*	**654 919**	**3 830 808**	**4 485 727**
Changes in net assets			
Surplus for the year	-	77 619	77 619
Total changes	-	77 619	77 619
Balance at 31 March 2022	**654 919**	**3 908 427**	**4 563 346**

CASH FLOW STATEMENT

	Note(s)	Economic entity		Controlling entity	
		2022 R'000	2021 Restated* R'000	2022 R'000	2021 Restated* R'000
Cash flows from operating activities					
Receipts					
Sale of goods and services		11 802 086	10 255 507	11 786 354	10 230 553
Grants		640 057	758 884	640 057	758 884
Interest income		198 896	165 774	198 435	165 255
		12 641 039	11 180 165	12 624 846	11 154 692
Payments					
Employee costs		(4 659 444)	(4 171 445)	(4 642 987)	(4 155 344)
Suppliers		(7 098 999)	(7 746 792)	(7 100 637)	(7 735 406)
Interest expense		(7 535)	(16)	(7 535)	(16)
		(11 765 978)	(11 918 253)	(11 751 159)	(11 890 766)
Net cash flows from operating activities	30	**875 061**	**(738 088)**	**873 687**	**(736 074)**
Cash flows from investing activities					
Purchase of property, plant and equipment	7	(318 928)	(386 042)	(318 866)	(386 042)
Purchase of intangible assets	9	(137)	(2 616)	(137)	(2 616)
Net cash flows from investing activities		**(319 065)**	**(388 658)**	**(319 003)**	**(388 658)**
Cash flows from financing activities					
Repayment of other financial liabilities		(4 920)	(4 960)	(4 920)	(4 960)
Finance lease payments		(19 840)	(21 982)	(19 840)	(21 982)
Net cash flows from financing activities		**(24 760)**	**(26 942)**	**(24 760)**	**(26 942)**
Net (decrease)/increase in cash and cash equivalents		**531 236**	**(1 153 688)**	**529 924**	**(1 151 674)**
Cash and cash equivalents at the beginning of the year		2 952 072	4 105 760	2 942 959	4 094 633
Cash and cash equivalents at the end of the year	6	**3 483 308**	**2 952 072**	**3 472 883**	**2 942 959**

STATEMENT OF COMPARISON OF BUDGET AND ACTUAL AMOUNTS

Budget on Accrual Basis

	Approved budget R'000	Adjustments R'000	Final Budget R'000	Actual amounts on comparable basis R'000	Difference between final budget and actual R'000	Reference
Economic entity						
Statement of Financial Performance						
Revenue						
Revenue from exchange transactions						
Sale of goods	2 680	-	2 680	13 694	11 014	
Rendering of services	9 542 150	-	9 542 150	11 583 914	2 041 764	40.1
Grant income recognised	290	(290)	-	8 107	8 107	
Fees earned	1 000	-	1 000	1 569	569	
Royalties received	-	-	-	2 095	2 095	
Bad debts recovered	1 000	-	1 000	1 365	365	
Internal Recoveries	21 822	-	21 822	59 484	37 662	
Teaching Income	66 816	-	66 816	87 066	20 250	
Sundry income	9 807	-	9 807	833	(8 974)	
Grant income recognised	20 000	-	20 000	188 855	168 855	40.2
Public Contributions and Donations	-	-	-	49 000	49 000	
Interest received	159 526	-	159 526	201 404	41 878	
Total revenue from exchange transactions	**9 825 091**	**(290)**	**9 824 801**	**12 197 386**	**2 372 585**	
Revenue from non-exchange transactions						
Transfer revenue						
Government grants & subsidies	640 077	-	640 077	640 057	(20)	
Total revenue	**10 465 168**	**(290)**	**10 464 878**	**12 837 443**	**2 372 565**	
Expenditure						
Personnel	(4 439 894)	-	(4 439 894)	(4 783 603)	(343 709)	
Depreciation and amortisation	(303 616)	-	(303 616)	(313 827)	(10 211)	
Finance costs	(3 529)	-	(3 529)	(8 546)	(5 017)	
Lease rentals on operating lease	(42 375)	-	(42 375)	(36 304)	6 071	
Debt Impairment	(25 000)	-	(25 000)	(1 227 658)	(1 202 658)	40.3
General Expenses	(5 537 649)	-	(5 537 649)	(6 390 744)	(853 095)	
Total expenditure	**(10 352 063)**	**-**	**(10 352 063)**	**(12 760 682)**	**(2 408 619)**	
Operating surplus	**113 105**	**(290)**	**112 815**	**76 761**	**(36 054)**	
Loss on disposal of assets and liabilities	-	-	-	(4 283)	(4 283)	
Gain on foreign exchange	-	-	-	2 399	2 399	
Fair value adjustments	-	-	-	1	1	
	-	**-**	**-**	**(1 883)**	**(1 883)**	
Surplus before taxation	**113 105**	**(290)**	**112 815**	**74 878**	**(37 937)**	
Taxation	-	-	-	1 553	1 553	
Actual Amount on Comparable Basis as Presented in the Budget and Actual Comparative Statement	**113 105**	**(290)**	**112 815**	**76 431**	**(36 384)**	

ACCOUNTING POLICIES

1. Presentation of Audited Annual Financial Statements

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.

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.

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. Estimates 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 an 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.

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 has made estimates of the selling price and direct cost to sell certain inventory items.

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.

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 the 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 of tangible assets are inherently uncertain and could materially change over time. They are significantly affected by a number of factors, 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 17 - 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. Management makes an adjustment to useful lives for certain assets that are fully deprecated at the end of the financial year.

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.

An acturial valuation 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 bond 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 15.

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 entity; and
- the cost of the item can be measured reliably.

Property, plant and equipment are initially measured at cost.

The cost of an item of property, plant and equipment is the purchase price and other costs attributable to bringing 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 from the price.

ACCOUNTING POLICIES (continued)

Where an asset is acquired through a non-exchange transaction, its cost is its fair value as at the 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.

Property, plant and equipment are subsequently carried at cost less accumulated depreciation and any impairment losses except for land and buildings plus sheep and horses. Buildings is carried at the 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 a revalued amount less accumulated impairment losses.

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 is 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.

Any decrease in an asset's carrying amount, as a result of a revaluation 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 net assets related to a specific item of property, plant and equipment is transferred directly to the retained accumulated surplus when the asset is derecognised.

Property, plant and equipment are depreciated on the straight line basis over their expected useful lives to their estimated residual value.

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 line	5 years
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 property	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 de-recognised 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 the 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.

1.5 Sheep and horses

Sheep and horses are donated and initally recognised at R1. They are subsequently carried the fair value.

1.6 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
Acquired Patents	Straight line	20 years
Acquired 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.

1.7 Investments in controlled entities

Economic entity audited annual financial statements

Investment in controlled entity is consolidated in the economic entity's 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.

1.8 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 for impairment or uncollectibility (through the use of an allowance account).

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 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 the 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.

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.

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
Payables from exchange transactions	Financial liability measured at amortised cost
Other financial liabilities	Financial liability measured at amortised cost

ACCOUNTING POLICIES (continued)

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.

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.

All financial assets measured at amortised cost are subject to an impairment review.

Gains and losses

For financial assets and financial liabilities measured at amortised 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 uncollectability 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 using an allowance account. The amount of the loss is recognised as a 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 was reversed. The amount of the reversal is recognised in surplus or deficit.

ACCOUNTING POLICIES (continued)

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.

The carrying amounts of the transferred assets 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 om that date. Any difference between the consideration received and the amounts recognised and derecognised is recognised as a 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 service, 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 service, a servicing asset is recognised for the service 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 a lender of debt instruments with substantially different terms is accounted for as having extinguished the original financial liability and a new financial liability being 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) is 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).

ACCOUNTING POLICIES (continued)

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.

Receivables from exchange and non-exchange transactions

Trade receivables are 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 a 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

Financial liabilities are measured at initial recognition at fair value and are subsequently measured at amortised cost using the effective interest rate method.

ACCOUNTING POLICIES (continued)

1.9 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.

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 a 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 the accounting surplus nor the 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 a future taxable surplus will be available against which the unused tax losses will be offset.

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.

1.10 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.

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 lease.

Minimum lease payments are apportioned between the finance charge and a 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.

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.

1.11 Inventories

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 economic entity.

1.12 Impairment of cash-generating assets

Cash-generating assets are assets used with the objective of generating a commercial return. Commercial return means that positive cash flows are expected to be significantly higher than the cost of the asset.

An asset's impairment is a loss in the future economic benefits or service potential of an asset, over and above the systematic recognition of the loss of the asset's future economic benefits or service potential through depreciation (amortisation).

A carrying amount is the amount at which an asset is recognised in the statement of financial position after deducting any accumulated depreciation and accumulated impairment losses thereon.

A cash-generating unit is the smallest identifiable group of assets used with the objective of generating a commercial return that generates cash inflows from continuing use that are largely independent of the cash inflows from other assets or groups of assets.

Costs of disposal are incremental costs directly attributable to the disposal of an asset, excluding finance costs and income tax expense.

Depreciation (amortisation) is the systematic allocation of the depreciable amount of an asset over its useful life.

Fair value less costs to sell is the amount obtainable from the sale of an asset in an arm's length transaction between knowledgeable, willing parties, less the cost of disposal.

Recoverable amount of an asset or a cash-generating unit is the higher its fair value less costs to sell and its value in use.

Useful life is the period of time over which an asset is expected to be used by the economic entity. Management's decisions in applying the criteria to classify assets as cash-generating or non-cash-generating assets are as follows:

ACCOUNTING POLICIES (continued)

Designation

At initial recognition, the economic entity designates an asset as non-cash-generating, or an asset or cash-generating unit as cash-generating. The designation is made on the basis of an economic entity's objective of using the asset.

The economic entity designates an asset or a cash-generating unit as cash-generating when:

- its objective is to use the asset or a cash-generating unit in a manner that generates a commercial return; such that
- the asset or cash-generating unit will generate positive cash flows, from continuing use and its ultimate disposal, that are expected to be significantly higher than the cost of the asset.

An asset used with the objective of generating a commercial return and service delivery, is designated either as a cash-generating asset or a non-cash-generating asset based on whether the economic entity expects to use that asset to generate a commercial return. When it is not clear whether the objective is to use the asset to generate commercial return, the economic entity designates the asset as a non-cash-generating asset and applies the accounting policy on Impairment of Non-Cash -Generating Assets, rather than this accounting policy.

Identification

When the carrying amount of a cash-generating asset exceeds its recoverable amount, it is impaired.

The economic entity assesses at each reporting date whether there is any indication that a cash-generating asset may be impaired. If any such indication exists, the economic entity estimates the recoverable amount of the asset.

Value in use

The value in use of a cash-generating asset is the present value of the estimated future cash flows expected to be derived from the continuing use of an asset and from its disposal at the end of its useful life.

When estimating the value in use of an asset, the economic entity estimates the future cash inflows and outflows to be derived from continuing use of the asset and from its ultimate disposal and the economic entity applies the appropriate discount rate to those future cash flows.

Basis for estimates of future cash flows

In measuring value in use the economic entity:

- base cash flow projections on reasonable and supportable assumptions that represent management's best estimate of the range of economic conditions that will exist over the remaining useful life of the asset. Greater weight is given to external evidence;
- base cash flow projections on the most recent approved financial budgets, but excludes any estimated future cash inflows or outflows expected to arise from future restructuring's or from improving or enhancing the asset's performance. Projections based on these budgets covers a maximum period of five years; and
- estimate cash flow projections beyond the period covered by the most recent budgets by extrapolating the projections based on the budgets using a steady growth rate for subsequent years. This growth rate does not exceed the long-term average growth rate for the products, industries in which the NHLS operates, or for the market in which the asset is used.

Composition of estimates of future cash flows

Estimates of future cash flows include:

- projections of cash inflows from the continuing use of the asset;
- projections of cash outflows that are necessarily incurred to generate the cash inflows from continuing use of the asset (including cash outflows to prepare the asset for use) and can be directly attributed, or allocated on a reasonable and consistent basis, to the asset; and
- net cash flows, if any, to be received (or paid) for the disposal of the asset at the end of its useful life.

Estimates of future cash flows exclude:

- cash inflows or outflows from financing activities; and
- income tax receipts or payments.

The estimate of net cash flows to be received (or paid) for the disposal of an asset at the end of its useful life is the amount that the economic entity expects to obtain from the disposal of the asset in an arm's length transaction between knowledgeable, willing parties, after deducting the estimated costs of disposal.

Discount rate

The discount rate is a pre-tax rate that reflects current market assessments of the time value of money, represented by the current risk-free rate of interest and the risks specific to the asset for which the future cash flow estimates have not been adjusted.

Recognition and measurement (individual asset)

If the recoverable amount of a cash-generating asset is less than its carrying amount, the carrying amount of the asset is reduced to its recoverable amount. This reduction is an impairment loss.

An impairment loss is recognised immediately in surplus or deficit.

Any impairment loss of a revalued cash-generating asset is treated as a revaluation decrease.

When the amount estimated for an impairment loss is greater than the carrying amount of the cash-generating asset to which it relates, the economic entity recognises a liability only to the extent that it is a requirement in the Standard of GRAP.

After the recognition of an impairment loss, the depreciation (amortisation) charge for the cash-generating asset is adjusted in future periods to allocate the cash-generating asset's revised carrying amount, less its residual value (if any), on a systematic basis over its remaining useful life.

Cash-generating units

If there is any indication that an asset may be impaired, the recoverable amount is estimated for the individual asset. If it is not possible to estimate the recoverable amount of the individual asset, the economic entity determines the recoverable amount of the cash-generating unit to which the asset belongs (the asset's cash-generating unit).

If an active market exists for the output produced by an asset or group of assets, that asset or group of assets is identified as a cash-generating unit, even if some or all of the output is used internally. If the cash inflows generated by any asset or cash- generating unit are affected by internal transfer pricing, the economic entity uses management's best estimate of future price(s) that could be achieved at arm's length transactions in estimating:

- the future cash inflows used to determine the asset's or cash-generating unit's value in use; and
- the future cash outflows used to determine the value in use of any other assets or cash-generating units that are affected by the internal transfer pricing.

Cash-generating units are identified consistently from period to period for the same asset or types of assets, unless a change is justified.

The carrying amount of a cash-generating unit is determined on a basis consistent with the way the recoverable amount of the cash-generating unit is determined.

An impairment loss is recognised for a cash-generating unit if the recoverable amount of the unit is less than the carrying amount of the unit. The impairment is allocated to reduce the carrying amount of the cash-generating assets of the unit on a pro rata basis, based on the carrying amount of each asset in the unit. These reductions in carrying amounts are treated as impairment losses on individual assets.

In allocating an impairment loss, the entity does not reduce the carrying amount of an asset below the highest of:

- its fair value less costs to sell (if determinable);
- its value in use (if determinable); and
- zero.

The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other cash-generating assets of the unit.

Where a non-cash-generating asset contributes to a cash-generating unit, a proportion of the carrying amount of that non- cash-generating asset is allocated to the carrying amount of the cash-generating unit prior to estimation of the recoverable amount of the cash-generating unit.

Reversal of impairment loss

The economic entity assesses at each reporting date whether there is any indication that an impairment loss recognised in prior periods for a cash-generating asset may no longer exist or may have decreased in value. If any such indication exists, the entity estimates the recoverable amount of that asset.

An impairment loss recognised in prior periods for a cash-generating asset is reversed if there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognised. The carrying amount of the asset is increased to its recoverable amount. The increase is a reversal of an impairment loss. The increased carrying amount of an asset attributable to a reversal of an impairment loss does not exceed the carrying amount that would have been determined (net of depreciation or amortisation) had no impairment loss been recognised for the asset in prior periods.

A reversal of an impairment loss for a cash-generating asset is recognised immediately in surplus or deficit. Any reversal of an impairment loss on a revalued cash-generating asset is treated as a revaluation increase.

After a reversal of an impairment loss is recognised, the depreciation (amortisation) charge for the cash-generating asset is adjusted in future periods to allocate the cash-generating asset's revised carrying amount, less its residual value (if any), on a systematic basis over its remaining useful life.

A reversal of an impairment loss for a cash-generating unit is allocated to the cash-generating assets of the unit pro rata with the carrying amounts of those assets. These increases in carrying amounts are treated as reversals of impairment losses for individual assets. No part of the amount of such a reversal is allocated to a non-cash-generating asset contributing service potential to a cash-generating unit.

In allocating a reversal of an impairment loss for a cash-generating unit, the carrying amount of an asset is not increased above the lower of:

- its recoverable amount (if determinable); and
- the carrying amount that would have been determined (net of amortisation or depreciation) had no impairment loss been recognised for the asset in prior periods.

The amount of the reversal of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit.

Redesignation

The redesignation of assets from a cash-generating asset to a non-cash-generating asset or from a non-cash-generating asset to a cash-generating asset only occur when there is clear evidence that such a redesignation is appropriate.

1.13 Share capital / contributed capital

Contributed capital is the initial funding received from the shareholder upon establishment of the National Health Laboratory Service.

Contributed capital is stated at par value.

1.14 Employee benefits

Employee benefits are all forms of consideration given by an entity 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 entity'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.

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; and
- 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.

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 as of the reporting date.

The entity recognises 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) that 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.

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 entity recognises 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 recognises 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. 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 are 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 occurred) and the effects of changes in actuarial assumptions. In measuring its defined benefit liability, the entity recognise actuarial gains and losses in surplus or deficit in the reporting period in which they occur.

The 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

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).

IIn 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.

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.

1.15 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.

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.

A provision is used only for expenditures for which the provision was originally recognised. Provisions are not recognised for future operating write offs.

Contingent assets and contingent liabilities are not recognised. Contingencies are disclosed in note 34.

1.16 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.

ACCOUNTING POLICIES (continued)

1.17 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.

Measurement

Revenue is measured at the fair value of the consideration received or receivable, net of trade discounts.

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.

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 recognised expenses that are recoverable.

Service revenue is recognised at the date when the service is deemed to have been delivered.

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.

1.18 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.

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 are required to be returned to the transferor if not deployed as specified.

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 entity.

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.

ACCOUNTING POLICIES (continued)

1.19 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 write-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.

1.20 Investment income

Investment income is recognised on a time-proportion basis using the effective interest method.

1.21 Borrowing costs

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.

1.22 Comparative figures

Where necessary, comparative figures have been reclassified to conform to changes in presentation in the current year.

1.23 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 year 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.

1.24 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 required with the exception for updating the note to the financial statements.

Irregular expenditure 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.

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.

1.25 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 that 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 as 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's 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 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.

1.26 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.

NOTES TO THE AUDITED ANNUAL FINANCIAL STATEMENTS

2. New standards and interpretations

2.1 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 2022 or later periods:

• GRAP 25 (as revised): Employee Benefits	01 April 2099	Unlikely there will be a material impact
• GRAP 104 (as revised): Financial Instruments	01 April 2025	Unlikely there will be a material impact
• GRAP 1 (amended): Presentation of Financial Statements	01 April 2023	Unlikely there will be a material impact

3. Inventories

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000
Raw materials, components	56	191	-	-
Work in progress	7 577	4 082	-	-
Finished goods	113	796	-	-
Consumable stores	829 717	1 115 759	829 729	1 115 882
	837 463	**1 120 828**	**829 729**	**1 115 882**

As at 31 March 2022 the NHLS inventory balance amounts to R0.8 billion (2021: R1.1 billion). The reduction in the balance is mostly due to the use of inventory items in relation to COVID-19. During the financial year ended 31 March 2022 the NHLS expensed inventory to the value of R4.8 billion (2021: R5.2 billion). The main inventory expense is driven by laboratory goods. An amount of R3 million (2021: R132.7 million) was written off during the financial year ended 31 March 2022, the write down mainly relates to obsolete and slow moving stock. There was also a reduction in the adjustment in relation to valuing COVID-19 inventory items to net replacement cost from R439.3 million in the prior to R5.4 million in the current year.

4. Receivables from exchange transactions

Trade debtors	6 574 640	5 128 233	6 573 624	5 125 267
Less: Allowance for impairment on trade debtors	(4 790 169)	(3 699 542)	(4 789 739)	(3 699 198)
	1 784 471	1 428 691	1 783 885	1 426 069
Prepayments	-	64	-	64
Deposits	4 948	2 440	4 948	2 440
Other receivables	3 913	3 721	3 887	3 693
Teaching Services*	151 265	130 274	151 265	130 274
	1 944 597	**1 565 190**	**1 943 985**	**1 562 540**

*Teaching services are in respect of revenue generated for teaching activities provided by the NHLS employees to the different institutions of higher learning.

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

4. Receivables from exchange transactions (continued)

Financial instruments				
Trade debtors	6 574 640	5 128 233	6 573 624	5 125 267
Allowance for impairment on trade debtors	(4 790 169)	(3 699 542)	(4 789 739)	(3 699 198)
Teaching Services*	151 265	130 274	151 265	130 274
	1 935 736	**1 558 965**	**1 935 150**	**1 556 343**
Non Financial instruments				
Prepayments	-	64	-	64
Deposits	4 948	2 440	4 948	2 440
Other receivables	3 913	3 721	3 887	3 693
	8 861	**6 161**	**8 835**	**6 133**
	1 944 597	**1 565 126**	**1 943 985**	**1 562 476**

Outstanding debt from KwaZulu-Natal Department of Health

Included in the trade debtors above is an amount of R2.812bn (2021: R2.792bn) owed by the KwaZulu-Natal Department of Health of which R2.574bn (2021: R2.575bn) has been impaired. An external audit was conducted on the amount disputed by the KwaZulu-Natal Department of Health. This amount was in relation to the audit, which concluded that an amount of R1.8bn is owed by KwaZulu-Natal Department of Health to the entity, however the parties involved have neither agreed nor acknowledged the outcome of the audit.

Outstanding debt from Gauteng Department of Health

The balance in the trade debtors balance above includes an amount owed by Gauteng Department of Health amounting to R1.394bn (2021: R719m) of which R741m (2021: R307m) has been impaired.

Outstanding debt from Eastern Cape Department of Health

Included in the trade debtors balance above is also an amount owed by Eastern Cape Department of Health amount to R567m (2021:R664m) of which R296m (2021:R303m) has been impaired.

Outstanding debt from Northern Cape Department of Health

The balance in the trade debtors above also includes an amount owed by Northern Cape Department of Health amounting to R354m (2021: R192m) of which R354m (2021: R98m) has been impaired.

Outstanding debt from North West Department of Health

The balance in the trade debtors above also includes an amount owed by North West Department of Health amounting to R345m (2021: R211m) of which R158m (2021: R61m) 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 2022, R1 284 733 R (2021: R1 625 304) were past due but not impaired.

4. Receivables from exchange transactions (continued)

The ageing of amounts past due but not impaired is as follows:

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000
1 month past due	430 267	1 162 139	429 845	1 159 384
2 months past due	791 874	409 743	791 713	409 667
3 months past due	62 592	53 422	62 534	53 397
	1 284 733	**1 625 304**	**1 284 092**	**1 622 448**

The maximum exposure is the carrying amount of Receivables from exchange transactions.

Trade and other receivables impaired

As at 31 March 2022, trade and other receivables of R4.8 bn (2021 R3.7 bn): were impaired and provided for.

The ageing of these loans is as follows:

3 to 6 months	4 790 169	3 699 542	4 789 739	3 699 198

Reconciliation of provision for impairment of trade and other receivables

Opening balance	3 699 542	3 698 666	3 699 198	3 698 576
Provision for impairment	1 092 766	2 516	1 092 680	2 262
Amounts written off as uncollectible	(2 139)	(1 640)	(2 139)	(1 640)
	4 790 169	**3 699 542**	**4 789 739**	**3 699 198**

5. Receivables from non-exchange transactions

Receivables from non-exchange transactions - gross	278 330	388 669	278 330	388 669
Allowance for impairment receivables from non exchange transactions	(243 463)	(106 433)	(243 463)	(106 433)
	34 867	**282 236**	**34 867**	**282 236**

6. Cash and cash equivalents

Cash and cash equivalents consist of:				
Cash on hand	227	207	207	206
Bank balances	20 213	50 802	19 823	50 728
Short-term deposits	3 462 868	2 901 063	3 452 853	2 892 025
	3 483 308	**2 952 072**	**3 472 883**	**2 942 959**
Cash and cash equivalents held by the entity that arenot available for use by the economic entity	503 126	625 129	503 126	625 129

The interest earned on cash at bank and short term deposits ranged from 3.95% to 4.82% (2021: 3.76% to 5.76%) and these deposits had an average maturity of 30 days.

7. Property, plant and equipment

Figures in Rand thousand

Economic entity	2022			2021		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Buildings	680 693	(86 519)	594 174	680 693	(65 298)	615 395
Buildings - air systems	250	(233)	17	250	(240)	10
Computer equipment	429 560	(201 644)	227 916	212 369	(121 876)	90 493
Furniture and fixtures	11 605	(2 987)	8 618	10 858	(2 453)	8 405
Laboratory equipment	1 025 781	(573 278)	452 503	927 211	(418 285)	508 926
Land	95 552	-	95 552	95 552	-	95 552
Leasehold property	17 684	(1 847)	15 837	37 587	(21 928)	15 659
Mobile units	41 032	(25 241)	15 791	36 544	(22 941)	13 603
Motor vehicles	94 019	(43 025)	50 994	173 210	(89 216)	83 994
Office Equipment	39 922	(25 431)	14 491	37 292	(19 667)	17 625
Plant and machinery	7 091	(3 987)	3 104	5 461	(2 934)	2 527
Total	**2 443 189**	**(964 192)**	**1 478 997**	**2 217 027**	**(764 838)**	**1 452 189**

Controlling entity	2022			2021		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Buildings	680 693	(86 519)	594 174	680 693	(65 298)	615 395
Buildings - air systems	250	(233)	17	250	(240)	10
Computer equipment	429 315	(201 482)	227 833	212 124	(121 692)	90 432
Furniture and fixtures	11 490	(2 926)	8 564	10 743	(2 400)	8 343
Laboratory equipment	1 021 389	(570 460)	450 929	922 819	(415 669)	507 150
Land	95 552	-	95 552	95 552	-	95 552
Motor vehicles	94 019	(43 025)	50 994	173 210	(89 216)	83 994
Leasehold property	17 684	(1 847)	15 837	37 587	(21 928)	15 659
Mobile units	41 032	(25 241)	15 791	36 544	(22 941)	13 603
Office equipment	39 869	(25 391)	14 478	37 239	(19 623)	17 616
Plant and machinery	7 091	(3 987)	3 104	5 461	(2 934)	2 527
Total	**2 438 384**	**(961 111)**	**1 477 273**	**2 212 222**	**(761 941)**	**1 450 281**

7. Property, plant and equipment (continued)

Reconciliation of property, plant and equipment - Economic entity - 2022

Figures in Rand thousand

	Opening balance	Additions	Donations Received	Disposals	Reclassification	Depreciation	Total
Buildings	615 395	-	-	-	-	(21 221)	594 174
Buildings - air systems	10	-	-	-	-	7	17
Computer equipment	90 493	219 380	-	(51)	37	(81 943)	227 916
Furniture and fixtures	8 405	1 040	-	(17)	(115)	(695)	8 618
Laboratory equipment	508 926	77 669	31 189	(467)	78	(164 892)	452 503
Land	95 552	-	-	-	-	-	95 552
Leasehold property	15 659	4 261	-	(155)	-	(3 928)	15 837
Mobile units	13 603	4 735	-	-	-	(2 547)	15 791
Motor vehicles	83 994	-	-	(3 502)	-	(29 498)	50 994
Office equipment	17 625	3 393	-	(77)	-	(6 450)	14 491
Plant and machinery	2 527	1 688	-	-	-	(1 111)	3 104
	1 452 189	**312 166**	**31 189**	**(4 269)**	**-**	**(312 278)**	**1 478 997**

Reconciliation of property, plant and equipment - Economic entity - 2021

	Opening balance	Additions	Disposals	Reclassification	Change in Accounting Estimates	Depreciation	Total
Buildings	636 411	481	-	(244)	-	(21 253)	615 395
Buildings - air systems	-	-	-	69	-	(59)	10
Computer equipment	73 585	21 262	(59)	(254)	39 523	(43 564)	90 493
Furniture and fixtures	3 856	1 374	(6)	211	3 623	(653)	8 405
Laboratory equipment	178 857	273 138	(3 099)	(6)	189 265	(129 229)	508 926
Land	95 552	-	-	-	-	-	95 552
Leasehold property	928	2 625	(15)	187	14 855	(2 921)	15 659
Mobile units	8 123	1 338	-	-	8 095	(3 953)	13 603
Motor vehicles	35 699	79 899	(56)	-	1 633	(33 181)	83 994
Office equipment	13 263	5 495	(95)	289	3 725	(5 052)	17 625
Other property, plant and equipment	217	-	-	(217)	-	-	-
Plant and machinery	1 676	430	-	-	1 196	(775)	2 527
	1 048 167	**386 042**	**(3 330)**	**35**	**261 915**	**(240 640)**	**1 452 189**

7. Property, plant and equipment (continued)

Reconciliation of property, plant and equipment - Controlling entity - 2022

Figures in Rand thousand

	Opening balance	Additions	Disposals	Reclassification	Change in Accounting Estimates	Depreciation	Total
Buildings	615 395	-	-	-	-	(21 221)	594 174
Buildings - air systems	10	-	-	-	-	7	17
Computer equipment	90 432	219 380	-	(51)	37	(81 965)	227 833
Furniture and fixtures	8 343	993	-	(17)	(115)	(640)	8 564
Laboratory equipment	507 150	77 669	31 189	(467)	78	(164 690)	450 929
Land	95 552	-	-	-	-	-	95 552
Leasehold property	15 659	4 261	-	(155)	-	(3 928)	15 837
Mobile units	13 603	4 736	-	-	-	(2 548)	15 791
Motor vehicles	83 994	-	-	(3 502)	-	(29 498)	50 994
Office equipment	17 616	3 393	-	(77)	-	(6 454)	14 478
Plant and machinery	2 527	1 688	-	-	-	(1 111)	3 104
	1 450 281	**312 120**	**31 189**	**(4 269)**	**-**	**(312 048)**	**1 477 273**

Reconciliation of property, plant and equipment - Controlling entity - 2021

	Opening balance	Additions	Donations Received	Disposals	Reclassification	Depreciation	Total
Buildings	636 411	481	-	(244)	-	(21 253)	615 395
Buildings - air systems	-	-	-	69	-	(59)	10
Computer equipment	73 531	21 262	(59)	(254)	39 485	(43 533)	90 432
Furniture and fixtures	3 805	1 374	(6)	211	3 593	(634)	8 343
Laboratory equipment	177 254	273 138	(3 099)	(6)	188 565	(128 702)	507 150
Land	95 552	-	-	-	-	-	95 552
Leasehold property	928	2 625	(15)	187	14 855	(2 921)	15 659
Mobile units	8 123	1 338	-	-	8 095	(3 953)	13 603
Motor vehicles	35 699	79 899	(56)	-	1 633	(33 181)	83 994
Office equipment	13 260	5 495	(95)	289	3 713	(5 046)	17 616
Other property, plant and equipment	217	-	-	(217)	-	-	-
Plant and machinery	1 676	430	-	-	1 196	(775)	2 527
	1 046 456	**386 042**	**(3 330)**	**35**	**261 135**	**(240 057)**	**1 450 281**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 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	-	15 353

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	2 286	6 955	2 286	6 937
Buildings	35 058	41 075	35 038	41 063
Motor vehicles	662	411	662	411
Laboratory equipment	58 147	51 005	57 176	50 081
	96 153	**99 446**	**95 162**	**98 492**

8. Sheep and horses

Economic entity	2022			2021		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Sheep and Horses	66	-	66	50	-	50

Reconciliation of sheep and horses - Economic entity - 2022

	Opening balance	Fair Value Adjustment	Total
Sheep and Horses	50	16	66

Reconciliation of sheep and horses - Economic entity - 2021

	Opening balance	Fair Value Adjustment	Total
Sheep and Horses	35	15	50

As at 31 March 2022, the economic entity owns 50 sheep (2021: 50) and 59 horses (2021: 59). The sheep blood are used for the testing of anti-venom. The horses are used for the production of anti-venom.

9. Intangible assets

Economic entity	2022			2021		
	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value
Computer software	9 737	(4 627)	5 110	9 638	(3 153)	6 485
Patents	60	(42)	18	60	(39)	21
Total	**9 797**	**(4 669)**	**5 128**	**9 698**	**(3 192)**	**6 506**

Controlling entity	2022			2021		
	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value
Computer software	9 737	(4 627)	5 110	9 638	(3 153)	6 485
Patents	60	(42)	18	60	(39)	21
Total	**9 797**	**(4 669)**	**5 128**	**9 698**	**(3 192)**	**6 506**

Reconciliation of intangible assets - Economic entity - 2022

	Opening balance	Additions	Disposals	Reclassification	Amortisation	Total
Computer software	6 485	137	(7)	-	(1 505)	5 110
Patents	21	-	-	-	(3)	18
	6 506	**137**	**(7)**	**-**	**(1 508)**	**5 128**

Reconciliation of intangible assets - Economic entity - 2021

	Opening balance	Additions	Disposals	Reclassification	Change in Accounting Estimates	Amortisation	Total
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**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

9. Intangible assets (continued)

Reconciliation of intangible assets - Controlling entity - 2022

	Opening balance	Additions	Disposals	Reclassification	Amortisation	Total
Computer software	6 485	137	(7)	-	(1 505)	5 110
Patents	21	-	-	-	(3)	18
	6 506	**137**	**(7)**	**-**	**(1 508)**	**5 128**

Reconciliation of intangible assets - Controlling entity - 2021

	Opening balance	Additions	Disposals	Reclassification	Change in Accounting Estimates	Amortisation	Total
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**

Reclassification represent corrections made in current year of intangible assets incorrectly classifiied as property, plant and equipment.

10. Investment in controlled entity

Name of company	% holding 2022	% holding 2021	Carrying amount 2022	Carrying amount 2021
South African Vaccine Producers (Pty) Ltd	100,00 %	100,00 %	-	-

The carrying amounts of controlled entities are shown net of impairment losses.

11. Loans to economic entity Controlled entities

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000
South African Vaccine Producers (Pty) Ltd	-	-	34 717	31 157
	-	-	34 717	31 157
Impairment of loans to controlled entity	-	-	(34 717)	(31 157)
	-	**-**	**-**	**-**

The Controlling entity has subordinated its rights to claim payments of debts of R34,717m (2021: R31,157m) 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.

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

12. Other financial liabilities

At amortised cost				
Onerous contract	-	4 920	-	4 920
Current liabilities				
At amortised cost	-	4 920	-	4 920

13. Finance lease obligation

Minimum lease payments due				
- within one year	-	19 802	-	19 802
- in second to fifth year inclusive	-	103	-	103
	-	19 905	-	19 905
less: future finance charges	-	(1 076)	-	(1 076)
Present value of minimum lease payments	**-**	**18 829**	**-**	**18 829**
Present value of minimum lease payments due				
- within one year	-	18 727	-	18 727
- in second to fifth year inclusive	-	102	-	102
	-	**18 829**	**-**	**18 829**
Non-current liabilities	-	102	-	102
Current liabilities	-	18 727	-	18 727
	-	**18 829**	**-**	**18 829**

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% (2021:11%).All leases have fixed repayments and no arrangements have been entered into for contingent rent. The depreciation on leased assets amounts to R11.5 million (2021: R63.9 million). The economic entity's obligations under finance leases are secured by the lessor's charge over the leased assets. Refer note 7.

14. Payables from exchange transactions

Trade payables *	372 108	411 763	371 700	411 318
Payments received in advanced - contract in process	4 478	87	-	-
Debtors with credit balances	358 183	139 168	358 183	139 168
Accrued expenses	710 480	568 349	709 456	567 842
Other payables **	28 950	25 358	28 950	25 358
	1 474 199	**1 144 725**	**1 468 289**	**1 143 686**

**** 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.***

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000
Financial instruments				
Trade payables	372 108	411 763	371 700	411 318
Payments received in advanced - contract in process	4 478	87	-	-
Debtors with credit balances	358 183	139 168	358 183	139 168
Accrued expense	710 480	568 349	709 456	567 842
	1 445 249	**1 119 367**	**1 439 339**	**1 118 328**
Non Financial instruments				
Other payables	28 950	25 358	28 950	25 358

15. 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	(1 023 296)	(919 388)	(1 023 296)	(919 388)
Non-current liabilities	(981 571)	(881 878)	(981 571)	(881 878)
Current liabilities	(41 725)	(37 510)	(41 725)	(37 510)
	(1 023 296)	**(919 388)**	**(1 023 296)**	**(919 388)**

Changes in the present value of the defined benefit obligation are as follows:

Opening balance	919 388	953 397	919 388	953 397
Contributions by plan participants	(39 706)	(36 728)	(39 706)	(36 728)
Net expense (income) recognised in the statement of financial performance	143 617	2 719	143 617	2 719
	1 023 299	**919 388**	**1 023 299**	**919 388**

Net expense recognised in the statement of financial performance

Current service cost	17 119	19 553	17 119	19 553
Interest cost	114 195	106 531	114 195	106 531
Actuarial losses (gains)	12 303	(123 365)	12 303	(123 365)
	143 617	**2 719**	**143 617**	**2 719**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000
Calculation of actuarial gains and losses				
Change in Modelling Methodology	(2 487)	-	(2 487)	-
Change in Real Discount Rate	(50 212)	48 777	(50 212)	48 777
Lower than expected healthcare cost inflation including changes in benefit options	19 010	21 798	19 010	21 798
Unexpected changes in membership	21 386	52 790	21 386	52 790
	(12 303)	**123 365**	**(12 303)**	**123 365**

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 2022. The economic assumptions have been set based on the duration of the liability as at 31 March 2021. At that date, the duration of the liability was 15 (2021:15.8) years; and therefore, the duration of 15 (2021:16) years was used to set the economic assumptions. Assumptions used in the report date::

Discount rates used	11,90 %	12,70 %	11,90 %	12,70 %
Expected rate of return on assets	7,10 %	7,50 %	7,10 %	7,50 %
Expected rate of return on reimbursement rights	8,60 %	9,00 %	8,60 %	9,00 %
Expected increase in healthcare costs	9,10 %	9,50 %	9,10 %	9,50 %

Discount rate:

The discount rate of 11.9% (2021:12.7%) 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 7.1% (2021: 7.5%) per annum. This assumption has been based on the relationship between the nominal bond curve and the real bond yield.

Income at Retirement:

Income 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 8.6% (2021:9.0%) per annum, based on the underlying assumption that individual remuneration increases 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 the 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 9.10% per annum compared to 9.5% per annum used in the previous valuation. In consultation with NHLS, assumptions made by the actuaries state that healthcare cost inflation exceed CPI inflation by an average of 2.57% per annum over the long term.

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

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:

	One percentage point increase	One percentage point increase point decrease	One percentage point increase	One percentage point increase point decrease
Effect on the aggregate of the service cost and interest cost	21 524	(19 505)	16 340	(13 701)
Effect on defined benefit obligation	147 654	(119 513)	147 654	(117 613)

Amounts for the current and previous four years are as follows:

	2022 '000	2021 '000	2020 '000	2019 '000	2018 '000
Defined benefit obligation	1 023 299	919 388	953 397	988 415	1 000 034

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.

16. Unspent conditional grants and receipts

Unspent conditional grants and receipts comprises of:				
Research grants	70 866	113 111	70 866	113 111
Movement during the year				
Balance at the beginning of the year	118 740	35 581	118 740	35 581
Additions during the year	39 320	122 282	39 320	122 282
Income recognition during the year	(87 194)	(44 752)	(87 194)	(44 752)
	70 866	**113 111**	**70 866**	**113 111**

17. Provisions

Reconciliation of provisions - Economic entity - 2022

	OpeningBalance	Additions	Utilised during the year	Reversed during the year	Total
Bonus provision [1]	578	2 060	(2 106)	-	532
DoH utility charges provision [2]	192 241	77 383	(70 900)	(59 120)	139 604
Leave pay provision [3]	318 199	74 445	(58 383)	-	334 261
Salaries provision [4]	163 671	-	-	-	163 671
Student bursary provision [5]	65	-	-	(65)	-
	674 754	**153 888**	**(131 389)**	**(59 185)**	**638 068**

Reconciliation of provisions - Economic entity - 2021

	OpeningBalance	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	74 745	(14 788)	(274)	318 199
Salaries provision [4]	163 671	-	-	-	163 671
Student bursary provision [5]	260	65	(260)	-	65
	841 392	**336 715**	**(17 320)**	**(486 033)**	**674 754**

Reconciliation of provisions - Controlling entity - 2022

	OpeningBalance	Additions	Utilised during the year	Reversed during the year	Total
Bonus provision [1]	578	2 060	(2 106)	-	532
DoH utility charges provision [2]	192 241	77 383	(70 900)	(59 120)	139 604
Leave pay provision [3]	318 199	74 445	(58 383)	-	334 261
Salaries provision [4]	163 671	-	-	-	163 671
Student bursary provision [5]	65	-	-	(65)	-
	674 754	**153 888**	**(131 389)**	**(59 185)**	**638 068**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

Reconciliation of provisions - Controlling entity - 2021

	OpeningBalance	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**

[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
- The 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. A reclassification of R71 million from provisions to accruals has been processed. During 2020/21, the financial year the NHLS developed and implementd 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.

[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 on the number of students awarded bursaries and amounts estimated using historical experiences.

18. Deferred tax

Deferred tax liability

Property, plant and equipment	(1 287)	(389)	-	-

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	(389)	(242)	-	-
Taxable temporary difference movement on property,plant and equipment	(898)	(147)	-	-
	(1 287)	**(389)**	**-**	**-**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

19. Revenue

Sale of goods	13 694	25 642	-	-
Rendering of services	11 583 914	9 752 964	11 583 914	9 752 964
Government grants and subsidies	640 057	758 884	640 057	758 884
Total Revenue	**12 237 665**	**10 537 490**	**12 223 971**	**10 511 848**
The amount included in revenue arising from exchanges of goods or services are as follows:				
Sale of goods	13 694	25 642	-	-
Rendering of services	11 583 914	9 752 964	11 583 914	9 752 964
	11 597 608	**9 778 606**	**11 583 914**	**9 752 964**
The amount included in revenue arising from non- exchange transactions is as follows:				
Transfer revenue				
Government grants and subsidies	640 057	758 884	640 057	758 884
	640 057	**758 884**	**640 057**	**758 884**

20. Cost of sales

Direct employee costs	4 300 514	3 903 058	4 285 186	3 887 822
Direct depreciation and impairments	309 791	(12 280)	309 719	(11 980)
Direct material expenses	5 507 090	6 559 713	5 504 168	6 552 027
	10 117 395	**10 450 491**	**10 099 073**	**10 427 869**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

21. Other income

Discount received	1 365	305	1 365	305
Miscellaneous other income*	8 107	42 383	8 107	42 383
Fees earned	1 569	2 284	1 569	2 284
Grant income recognised	188 855	162 496	188 855	162 496
Internal recoveries	364	17 163	364	17 163
Public contributions and donations **	49 000	250 869	49 000	250 869
Utilities provision write-off ***	59 120	485 759	59 120	485 759
Gain on exchange differences	2 399	-	2 399	-
Royalties received	2 095	2 063	2 095	2 063
Sundry income	833	826	833	826
Teaching income	87 066	87 532	87 066	87 532
	400 773	**1 051 680**	**400 773**	**1 051 680**

* Miscellaneous and other income 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 the Contract Laboratory Services. In the current financial year the decrease is due to billing for COVID-19 Antigen goods provided to the Provincial Departments of Health.

** During the 2020/21 financial period the NHLS received the funding in 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 implemented 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	1 365	305	1 365	305
Miscellaneous other income*	8 107	42 383	8 107	42 383
Fees earned	1 569	2 284	1 569	2 284
Internal recoveries	364	17 163	364	17 163
Utilities provision write-off	59 120	485 759	59 120	485 759
Gain or loss on exchange differences	2 399	-	2 399	-
Royalties received	2 095	2 063	2 095	2 063
Sundry income	833	826	833	826
Teaching income	87 066	87 532	87 066	87 532
	162 918	**638 315**	**162 918**	**638 315**

Transfers

Grant income recognised	188 855	162 496	188 855	162 496
Public contributions and Donations	49 000	250 869	49 000	250 869
	237 855	**413 365**	**237 855**	**413 365**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

22. Operating deficit

Operating deficit for the year is stated after accounting for the following:

Operating lease charges				
Premises				
• Straight-lined	4 703	4 576	4 649	4 462
Motor vehicles				
• Straight-lined	(966)	-	(966)	-
Equipment				
• Straight-lined	38 787	42 470	38 628	42 323
	42 524	**47 046**	**42 311**	**46 785**
Loss on sale of property, plant and equipment	4 283	3 335	4 283	3 335
Amortisation on intangible assets	1 418	1 151	1 418	1 151
Depreciation on property, plant and equipment	312 409	(21 761)	312 239	(21 560)
Employee costs	4 783 603	4 202 399	4 767 146	4 186 298

23. Interest income

Interest revenue				
Bank	139 450	128 952	139 032	128 453
Interest received - debtors	61 954	34 753	61 911	34 733
	201 404	**163 705**	**200 943**	**163 186**

24. Interest expense

Bank	2	15	2	15
Finance leases	1 011	3 681	1 011	3 681
Late payment of tax	7 374	1	7 374	1
Other interest paid	159	-	159	-
	8 546	**3 697**	**8 546**	**3 697**

25. Taxation

Major components of the tax (income) expense				
Current				
Local income tax - current period	(2 451)	333	-	-
Deferred				
Originating and reversing temporary differences	898	147	-	-
	(1 553)	**480**	**-**	**-**

Reconciliation of the tax expense

Reconciliation between applicable tax rate and average effective tax rate.

Applicable tax rate	28,00 %	28,00 %	- %	- %

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

26. Employee related costs

Basic	3 424 972	3 081 398	3 412 921	3 069 650
Bonus	187 392	161 735	186 617	160 990
Defined contribution plans	412 205	250 790	411 061	249 667
External bursaries	1 955	375	1 955	345
Leave pay provision charge	44 592	76 896	44 376	76 734
Long-term benefits - incentive scheme	4 811	3 405	4 750	3 380
Medical aid - company contributions	248 877	232 250	247 794	231 090
Other allowances	251 069	211 875	251 069	211 875
Other short term costs	135 498	131 804	134 846	131 098
Skills Development Levy (SDL)	38 737	25 469	38 593	25 328
Training	229	146	32	17
Unemployment Insurance Fund (UIF)	17 021	14 828	16 950	14 761
Workers Compensation Assistance (WCA)	16 245	11 428	16 182	11 363
	4 783 603	**4 202 399**	**4 767 146**	**4 186 298**

Employee costs are split into cost of sales and general expenses as follows:

Cost of sales - employee costs	4 300 514	3 903 058	4 285 186	3 887 822
General expenses - employee costs	483 089	299 341	481 960	298 476
	4 783 603	**4 202 399**	**4 767 146**	**4 186 298**

27. Operating expenses

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000
Advertising	543	889	543	895
Archiving and Storage	9 393	8 497	9 393	8 497
Auditors remuneration	8 710	12 511	8 710	12 511
Bad debts written off	2 139	1 640	2 139	1 640
Bank charges	13 217	9 766	13 172	9 725
Cleaning	3 293	8 107	3 293	8 094
Computer expenses	1 457	2 415	1 418	2 414
Conferences and seminars	564	56	545	56
Consulting and professional fees	48 918	67 873	48 674	67 717
Consumables	17 893	18 335	17 839	18 303
Contributions to debt impairment provision	1 227 658	32 654	1 231 130	30 559
Debt collection	923	952	923	952
Delivery expenses	2 420	2 817	2 421	2 806
Depreciation, amortisation and impairments	4 036	(8 315)	3 938	(8 429)
Discount allowed	37 541	35 674	37 541	35 674
Employee costs	483 089	299 341	481 960	298 476
Entertainment	-	2	-	2
Insurance	9 306	9 173	9 306	9 173
Lease rentals on operating lease	36 304	41 000	36 262	40 875
Legal expenses	39 729	20 494	39 729	20 492
Loss on disposal of assets and liabilities	4 283	3 335	4 283	3 335
Gain or loss on exchange differences	-	2 127	-	2 127
Medical expenses	3	-	3	-
Minor assets	5 092	8 929	5 092	8 929
Motor vehicle expenses	1 198	11 093	1 198	11 093
Other expenses	13	870	15	869
Packaging	10 457	9 552	10 338	9 407
Petrol and oil	17 946	10 447	17 946	10 447
Postage and courier	604	329	604	329
Printing and stationery	55 203	44 624	55 181	44 585
Project Management expenses	13	690	13	690
Promotions	40	2	40	2
Promotions and sponsorships	33	38	33	38
Repairs and maintenance	38 006	48 442	37 986	48 412
Research Trust	93	5	93	5
Royalties and license fees	1 607	1 582	1 607	1 582
Security	1 023	4 559	1 023	4 559
Software development expenses	19 557	15 546	19 557	15 546
Software expenses	178 967	176 177	178 950	176 177
Staff welfare	6 129	6 078	6 064	5 911
Subscriptions and membership fees	4 137	4 763	4 078	4 740
Telephone and fax	90 944	124 541	90 876	124 459
Training	40 661	26 077	40 661	26 077
Travel - local	18 677	11 412	18 667	11 412
Travel - overseas	15	24	15	24
Utilities	197 190	157 717	197 190	157 717
	2 639 024	**1 232 840**	**2 640 449**	**1 228 904**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

28. Auditors' remuneration

Audit Fees - current year	8 665	11 533	8 665	11 533
Fees for other services	45	978	45	978
	8 710	**12 511**	**8 710**	**12 511**

29. Depreciation and amortisation

Depreciation and amortisation - Cost of sales	309 791	(12 280)	309 719	(11 980)
Depreciation and amortisation - General expenses	4 036	(8 315)	3 938	(8 429)
	313 827	**(20 595)**	**313 657**	**(20 409)**

30. Cash generated from (used in) operations

Surplus for the year	76 431	65 382	77 619	66 244
Adjustments for:				
Depreciation and amortisation	313 799	(20 595)	313 569	(20 409)
Loss on sale of assets and liabilities	4 281	3 335	4 281	3 335
Fair value adjustments	(1)	(15)	-	-
Finance costs	1 011	3 681	1 011	3 681
Debt impairment	1 227 658	32 654	1 231 130	30 559
Movements in retirement benefit assets and liabilities	103 908	(34 009)	103 908	(34 009)
Movements in provisions	(36 686)	(166 638)	(36 686)	(166 638)
Movement in tax receivable and payable	(2 451)	333	-	-
Annual charge for deferred tax	898	147	-	-
Other non-cash items	5	178	6	178
Donations of Assets	(24 456)	-	(24 456)	-
Changes in working capital:				
Inventories	283 365	(954 706)	286 153	(955 580)
Receivables from exchange transactions	(1 607 065)	(332 166)	(1 612 575)	(329 383)
Receivables from non-exchange transactions	247 369	168 009	247 369	168 009
Payables from exchange transactions	329 474	418 849	324 603	420 409
VAT	(234)	(57)	-	-
Unspent conditional grants and receipts	(42 245)	77 530	(42 245)	77 530
	875 061	**(738 088)**	**873 687**	**(736 074)**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

31. Tax refunded

Balance at beginning of the year	(2 026)	(1 693)	-	-
Current tax for the year recognised in surplus or deficit	2 451	(333)	-	-
Balance at end of the year	(425)	2 026	-	-
	-	-	-	-

32. Financial instruments disclosure

Categories of financial instruments

Economic entity - 2022

Financial assets

	At amortised cost R'000	Total R'000
Receivables from exchange transactions	1 935 736	1 935 736
Receivables from non-exchange transactions	34 867	34 867
Cash and cash equivalents	3 483 308	3 483 308
	5 453 911	**5 453 911**

Financial liabilities

	At amortised cost R'000	Total R'000
Payables from exchange transactions	1 445 249	1 445 249

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

32. Financial instruments disclosure (continued)

Economic entity - 2021

Financial assets

	At amortised cost R'000	Total R'000
Receivables from exchange transactions	1 558 965	1 558 965
Receivables from non-exchange transactions	262 236	262 236
Cash and cash equivalents	2 952 072	2 952 072
	4 773 273	**4 773 273**

Financial liabilities

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

	At amortised cost R'000	Total R'000
Payables from exchange transactions	1 119 367	1 119 367

Controlling entity - 2022

Financial assets

	At amortised cost R'000	Total R'000
Receivables from exchange transactions	1 943 985	1 943 985
Receivables from non-exchange transactions	34 867	34 867
Cash and cash equivalents	3 472 883	3 472 883
	5 451 735	**5 451 735**

Financial liabilities

	At amortised cost R'000	Total R'000
Payables from exchange transactions	1 439 339	1 439 339

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

32. Financial instruments disclosure (continued)

Controlling entity - 2021

Financial assets

	At amortised cost R'000	Total R'000
Trade and other receivables from exchange transactions	1 562 540	1 562 540
Other receivables from non-exchange transactions	282 236	282 236
Cash and cash equivalents	2 942 959	2 942 959
	4 787 735	**4 787 735**

Financial liabilities

	At amortised cost R'000	Total R'000
Payables from exchange transactions	1 118 328	1 118 328

Financial instruments in Statement of financial performance

Economic entity - 2022

	At amortised cost R'000	Total R'000
Interest income	201 404	201 404
Interest expense	(161)	(161)
	201 243	**201 243**

Economic entity - 2021

	At amortised cost R'000	Total R'000
Interest income	163 705	163 705
Interest expense	(3 697)	(3 697)
	160 008	**160 008**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

32. Financial instruments disclosure (continued)

Controlling entity - 2021

	At amortised cost R'000	Total R'000
Interest income	200 943	200 943
Interest expense	(161)	(161)
	200 782	**200 782**

Controlling entity - 2021

	At amortised cost R'000	Total R'000
Interest income	163 186	163 186
Interest expense	(3 697)	(3 697)
	159 489	**159 489**

33. Commitments

Authorised capital expenditure

Already contracted for but not provided for				
• Property, plant and equipment	103 603	205 348	103 603	205 348
Not yet contracted for and authorised by member				
• Property, plant and equipment	-	5 825	-	5 825
Total capital commitments				
Already contracted for but not provided for	103 603	205 348	103 603	205 348
Not yet contracted for and authorised by member	-	5 825	-	5 825
	103 603	**211 173**	**103 603**	**211 173**

Authorised operational expenditure

Already contracted for but not provided for				
• Current Expenditure	1 801 266	1 938 019	1 801 266	1 938 019
Not yet contracted for and authorised by member				
• Current Expenditure	94 917	48 743	94 917	48 743
Total operational commitments				
Already contracted for but not provided for	1 801 266	1 938 019	1 801 266	1 938 019
Not yet contracted for and authorised by member	94 917	48 743	94 917	48 743
	1 896 183	**1 986 762**	**1 896 183**	**1 986 762**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

33. Commitments (continued)

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	3 170	10 297	3 170	10 297
• - in second to fifth year inclusive	682	1 698	682	1 698
	3 852	**11 995**	**3 852**	**11 995**

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.

34. Contingencies

Claims lodged for damages:				
WSU salaries dispute	-	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	432	3 737	432	3 737
Chien	-	3 245	-	3 245
Sthathu / SKG	-	2 396	-	2 396
H Molotsi	1 759	-	1 759	-
M Baijnath	180	-	180	-
G Mathebula	900	-	900	-
Z Phasha	237	-	237	-
Bakhuti Trading CC	251	-	251	-
Fredericks	-	-	-	-
G Sethosa	-	-	-	-
G De Gita	-	-	-	-
J Mogale and S Zulu	-	-	-	-
L Gqweta	-	-	-	-
	67 188	**88 116**	**67 188**	**88 116**

34. Contingencies (continued)

The WSU had claimed that the salaries of HODs, Medical Scientists and Technologists are owed by the NHLS for the period 2007 - 2013. The amount was 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.

There is also a dispute before the Labour court on the deduction of monies that were allegedly overpaid to the Dr Z Moorad and Dr A Jali which amounts to R0.2 million.

There is also a dispute before the High Court with regards to a contractual dispute with Rapid IT Solution which amounts to now amounts to R0.4 million. The NHLS attorneys confirmed that the inital amount of R3.7 million as claimed will no longer be applicable. The only amount to be applicable in this review application is the R0.4 million.

The Chien matter was in favour of the NHLS as they have withdrawn the review application

The Sthathu and SKG matter was resolved in the favour of the NHLS.

There is also another matter between H Molotsi where the NHLS is being sued for an amount of R1,7 million

There is also another matter between Bakuthi Trading CC where the NHLS is being sued for an amount of R0.2 million.

There are also labour matters between the NHLS and the following:

a) M Baijnath for an amount of R0.2 million
b) G Mathebula for an amount of R0.9 million
c) Z Phasha for an amount of R0.2 million
d) Fredericks for which the amount has not been determined as the matter is still under review
e) G Sethosa for which the amount has not been determined as the matter is still under review
f) G De Gita for which the amount has not been determined as the matter is still under review
g) J Mogale and S Zulu for which the amount has not been determined as the matter is still under review
h) L Gqweta for which the amount has not been determined as the matter is still under review

The intention of the NHLS is to defend all other cases and the legal opinion is of the view that the NHLS is in a favourable legal position to succeed.

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

34. Contingencies (continued)

The NHLS has not concluded wage negotiations with regard to the annual salary adjustment for the 2021/22 financial period for NHLS employees who 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 Vuuren	1 630	1 630	1 630	1 630
Prof Wade	18 283	-	18 286	-
Hamilton Ndlovu	159 156	-	159 156	-
	179 069	**1 630**	**179 072**	**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 a breach of penalty.

There is a matter between the NHLS and Prof Wade where NHLS is claiming R18.2 million.

There is a matter between the NHLS and Hamilton Ndlovu where Hamilton Ndlovu is liable to pay the NHLS R159.2 million.

35. Related parties

Relationships

Board Members	Prof Eric Buch Prof Jeffrey Mphahlele Dr Lesley Bamford Mr Nick Buick Prof Mpho Klass Kgomo Mr Jonathan Mallet Prof Thanyani Mariba Dr Siseko Martin Dr Balekile Mzangwa Mr Koena Nkoko Dr Naledzani Ramalivhana Mr Michael Sachs Prof Tivani Mashamba - Thompson Mrs Nicolene van der Westhuizen Ms Thandi Msimango Dr Mahlane Phalane
Controlling entity	National Department of Health
Controlled Entity	South African Vaccine Producers (Pty) Ltd

35. Related parties (continued)

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 Northen Cape Department of Health Mpumalanga Department of Health Free State Department of Health
Universities	University of Cape Town Stellenbosch University University of Western Cape University of Free State University of the 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 Mr S.T. Hlongwane (Chief Information Officer) Dr S.M. Kgalamono (NIOH Director) Prof K.P. Mlisana (AARQA Executive)| Ms M Mkhwanazi (Executive: Human Resources) Prof A.J. Puren (NICD Director)

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

35. Related parties (continued)

Amounts included in Trade receivable regarding related parties

By Region				
Eastern Cape	570 499	667 200	570 499	667 200
Free State	275 618	162 611	275 618	162 611
Gauteng	1 583 840	704 444	1 583 840	704 444
KwaZulu-Natal	2 432 273	2 396 530	2 432 273	2 396 530
Limpopo	51 138	40 103	51 138	40 103
Mpumalanga	71 157	79 848	71 157	79 848
North West	350 459	211 741	350 459	211 741
Northern Cape	355 608	193 642	355 608	193 642
Western Cape	45 898	59 604	45 898	59 604
	5 736 490	**4 515 723**	**5 736 490**	**4 515 723**

Provision for doubtful debts related to outstanding balances with related parties

By Region				
Gauteng	855 404	165 809	855 404	165 809
KwaZulu-Natal	2 574 334	2 575 051	2 574 334	2 575 051
	3 429 738	**2 740 860**	**3 429 738**	**2 740 860**

Amounts in Trade receivables regarding related parties

By Segment				
Anti-retroviral programmes	765 944	384 455	765 944	384 455
Correctional Services	7 104	6 879	7 104	6 879
Defense	7 178	6 319	7 178	6 319
Health Clinics	2 063 828	1 400 150	2 063 828	1 400 150
Hospitals	2 878 854	2 714 851	2 878 854	2 714 851
Other Public Entities	2 125	1 843	2 125	1 843
Universities	8 772	1 226	8 772	1 226
Municipalities	2 685	-	2 685	-
	5 736 490	**4 515 723**	**5 736 490**	**4 515 723**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

35. Related parties (continued)

Amounts included in Trade Payables regarding related parties

By Province				
Eastern Cape	-	73	-	73
Free State	-	38	-	38
Gauteng	1 114	3 329	1 114	3 329
KwaZulu-Natal	44	252	44	252
Limpopo	108	98	108	98
North West	479	462	479	462
Western Cape	1 394	949	1 394	949
	3 139	**5 201**	**3 139**	**5 201**

Amounts included in Trade Payables regarding related parties

By Segment				
Contract Laboratory Services	23	16	23	16
Municipalities	1 020	3 355	1 020	3 355
National Public Entities	753	681	753	681
Provincial Public Entities	-	33	-	33
Universities	1 343	1 116	1 343	1 116
	3 139	**5 201**	**3 139**	**5 201**

Related party transactions

Services billed to related parties

Region				
Eastern Cape	1 210 403	1 103 487	1 210 403	1 103 487
Free State	605 891	507 107	605 891	507 107
Gauteng	3 073 808	2 627 362	3 073 808	2 627 362
KwaZulu-Natal	2 881 779	2 514 243	2 881 779	2 514 243
Limpopo	581 560	532 565	581 560	532 565
Mpumalanga	736 540	619 624	736 540	619 624
North West	652 851	519 480	652 851	519 480
Northern Cape	285 276	227 116	285 276	227 116
Western Cape	1 274 505	1 057 085	1 274 505	1 057 085
	11 302 613	**9 708 069**	**11 302 613**	**9 708 069**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

35. Related parties (continued)

Services billed to related parties

By Segment				
Anti-retroviral	2 450 394	3 160 407	2 450 394	3 160 407
Correctional Services	28 584	35 335	28 584	35 335
Defense	44 357	32 268	44 357	32 268
Health Clinics	3 152 370	2 502 554	3 152 370	2 502 554
Hospitals	4 532 675	3 865 234	4 532 675	3 865 234
Municipalities	15 280	14 058	15 280	14 058
Other Public entities	12 902	13 674	12 902	13 674
Universities	66 051	84 539	66 051	84 539
	10 302 613	**9 708 069**	**10 302 613**	**9 708 069**

Purchases from related parties

Region				
Eastern Cape	2 895	2 940	2 895	2 940
Free State	12 733	7 493	12 733	7 493
Gauteng	143 475	91 726	143 475	91 726
KwaZulu-Natal	1 206	1 263	1 206	1 263
Limpopo	181	433	181	433
North West	10	512	10	512
Western Cape	39 646	32 207	39 646	32 207
	200 146	**136 574**	**200 146**	**136 574**

Purchases from related parties

By Segment				
Contract Laboratory Services	20 751	32 516	20 751	32 516
Municipalities	113 468	49 202	113 468	49 202
National Public Entities	17 926	15 994	17 926	15 994
Provincial Public Entities	124	176	124	176
Universities	47 877	38 686	47 877	38 686
	200 146	**136 574**	**200 146**	**136 574**

NOTES TO THE AUDITED ANNUAL FINANCIAL STATEMENTS (continued)

36. 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

2022

	Salaries	Retirement Contribution	Medical Contribution	Expense Allowance	Other**	Leave Pay Out	Total
Dr K. Chetty (Chief Executive Officer)	2 456	215	-	40	26	-	2 737
Mr M. Sass (Chief Financial Officer)**	2 290	167	68	-	2 287	452	5 264
Mr M.J. Shai (Acting Chief Financial Officer)	1 950	-	-	-	24	-	1 974
Adv M. M. Mphelo (Company Secretary)	2 034	178	-	5	25	-	2 242
Mr S.T. Hlongwane (Chief Information Officer)	1 751	163	112	2	22	-	2 050
Dr S.M. Kgalamono (NIOH Director)	2 068	230	78	6	26	-	2 408
Prof K.P. Mlisana (AARQA Executive)	2 226	208	150	6	28	-	2 618
Ms M. Mkhwanazi (Executive: Human Resources from 01 June 2021)	1 644	152	88	-	21	-	1 905
M. Saffer (SAVP Director)	899	79	-	5	13	-	996
Prof A.J. Puren (NICD Director)	1 600	154	91	-	20	-	1 865
	18 918	**1 546**	**587**	**64**	**2 492**	**452**	**24 059**

***** The amount under other is mainly due to an agreement reached between the NHLS and the employee due the early termination of the fixed term contract***

36. Prescribed Officers and Board members' emoluments - R'000s

2021

	Salaries	Retirement Contribution	Medical Contribution	Expense Allowance	Other**	Bonus	Total
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.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
Ms 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**

***** Other payments include company contributions for skills development, UIF, expense recoveries and long service awards.***

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

36. Prescribed Officers and Board members' emoluments - R'000s (continued)

Service contracts

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 5 years.

Non-executive board members

2022

	Member's fees	Total
Prof Eric Buch	233	233
Prof Jeffrey Mphahlele	90	90
Prof Thanyani Mariba	126	126
Dr Siseko Martin	77	77
Mr Michael Sachs	88	88
Ms Sphiwe Mayinga	78	78
Prof Tivani Mashamba - Thompson	44	44
Prof Mary Ross	38	38
	774	**774**

2021

	Member's fees	Committeesfees	Total
Dr Balekile Mzangwa	-	6	6
Prof Eric Buch	308	-	308
Prof Thanyani Mariba	162	-	162
Dr Siseko Martin	100	-	100
Dr Balekile Mzangwa	159	-	159
Prof Mary Ross	156	-	156
Mr Michael Shingange	98	-	98
Mr Michael Sachs	85	-	85
	1 068	**6**	**1 074**

Other fees relate to travel re-imbursement, out-of-pocket expenses and other company contributions

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

37. 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. The Economic Entity Treasury identifies and evaluates financial risks in close cooperation 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, the 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 R3.5bn (2021: R2.9bn).

The economic entity's liquidity 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.

Economic entity

At 31 March 2022	Less than 1 year	Between 1 and 2 years
Payables from exchange transactions	1 474 199	-

At 31 March 2021	Less than 1 year	Between 1 and 2 years
Payables from exchange transactions	1 144 725	-
Other financial liabilities	4 920	-
Finance lease obligation	18 727	102

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

37. Risk Management (continued

Controlling entity

At 31 March 2022	Less than 1 year	Between 1 and 2 years
Payables from exchange transactions	1 468 289	-

At 31 March 2021	Less than 1year	Between 1 and 2 years
Payables from exchange transactions	1 143 686	-
Other financial liabilities	4 920	-
Finance lease obligation	18 727	102

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.

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 Department of Health and Gauteng Department of Health, a total doubtful debt allowance of R4.7bn (2021: R2.876bn) has been raised for these Departments. Trade receivables are interest-bearing and are generally on 30-days 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 additional interest owed to NHLS.

38. Irregular expenditure

Opening balance as previously reported	2 805 627	2 205 382	2 805 627	2 205 382
Correction of prior period error	-	(178 394)	-	(178 394)
Opening balance as restated	**2 805 627**	**2 026 988**	**2 805 627**	**2 026 988**
Add: Irregular Expenditure - current	665 462	778 639	665 462	778 639
Add: Irregular Expenditure - prior period	618 882	-	618 882	-
Closing balance	**4 089 971**	**2 805 627**	**4 089 971**	**2 805 627**
Analysis of awaiting condonation per ageclassification				
Current year	665 462	778 639	665 462	778 639
Prior years	3 424 509	2 026 988	3 424 509	2 026 988
	4 089 971	**2 805 627**	**4 089 971**	**2 805 627**

		Economic entity		Controlling entity	
		2022 R'000	2021 R'000	2022 R'000	2021 R'000

38. Irregular Expenditure (continued)

Incidents/cases identified in the current year include those listed below:

	Disciplinary steps taken/ criminal proceedings				
Expired Contracts	None as tender is in progress	292 298	254 902	292 298	254 902
No Tender Procedures followed	None as tender is in progress	339 062	315 016	339 062	315 016
Non compliance with regulations	Matters under investigation	7 167	-	7 167	-
Contract overspend	NHLS had legal obligation to pay	26 935	35 978	26 935	35 978
Improper procument procedures followed	Under litigation	618 882	172 743	618 882	172 743
		1 284 344	**778 639**	**1 284 344**	**778 639**

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)**

Expired contract

The expired contracts primarily relate to cleaning services, printing services, IT services and document management services. There are tenders in process to award valid contracts or services have been insourced.

Contract overspend

The contract spend is as a result of litigation against the NHLS. The NHLS was legally bound to the expired contract. This contract was terminated in December 2021 and a new contract has been awarded.

No tender procedures

This mainly relates to essential goods and services procured by the NHLS pending the processing and the awarding of valid contracts.

Non Compliance with regulations

Insufficient Standard Bidding Documents obtained at the time of procurement.

38. Irregular Expenditure (continued)

Improper procurement procedure followed – Emergency procurement of COVID-19 Personal Protective Equipment (see paragraph b. below)

a. Matters under Assessment

At the time of reporting for the 2021/22 financial year, there were matters amounting to R115 199 032 under assessment in line with the Irregular Expenditure Framework as published by the National Treasury. Assessment in this regard refers to tests 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. These assessments may result in additional irregular expenditure but the nature and extent at reporting date have not been established.

b. Matters confirmed for COVID-19 Emergency Procurement

Irregular expenditure to the amount of R 791 623 789 has been confirmed for the 2021/22 period. This expenditure relates to procurement not in line with Instruction Notes issued by the National Treasury pertaining to Emergency Procurement in response to the National State of Disaster. External and internal investigations are ongoing. These have resulted in litigation, consequence management and prosecution. To date the NHLS has been awarded recovery of R159m following successful litigation. Litigation and prosecution are an on-going for certain COVID-19 related procurement items.

39. 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 - 2021

	Note	As previously reported	Correction of error	Reclassification	Restated
Receivables from exchange transactions [1]	4	1 443 164	15 593	106 433	1 565 190
Receivables from non exchange transactions [2]	5	414 474	(25 805)	(106 433)	282 236
Property, plant and equipment [3]	7	1 330 849	121 390	-	1 452 239
Payables from exchange transactions [4]	14	(1 140 172)	(4 552)	-	(1 144 724)
Unspent conditional grants	16	(17 548)	(95 563)	-	(113 111)
Accumulated surplus		(3 834 840)	(11 063)	-	(3 845 903)
		(1 804 073)	**-**	**-**	**(1 804 073)**

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

Controlling entity - 2021

	Note	As previously reported	Correction of error	Reclassification	Restated
Receivables from exchange transactions [1]	4	1 440 514	11 041	110 985	1 562 540
Receivables from non exchange transactions [2]	5	414 474	(25 805)	(106 433)	282 236
Property, plant and equiment [3]	7	1 328 891	121 390	-	1 450 281
Payables from exchange transactions [4]	14	(1 139 133)	-	(4 552)	(1 143 685)
Unspent conditional grants	16	(17 548)	(95 563)	-	(113 111)
Accumulated surplus		(3 819 735)	(11 063)	-	(3 830 798)
		(1 792 537)	**-**	**-**	**(1 792 537)**

[1] During the year, it was noted that there was an adjustment required for Receivables from exchange transactions mostly as a result of unrecognised unspent conditional grants. The reclassification is in relation to the provision for doubtful debts in relation to Receivables from non-exchange transactions.

[2] During the year, it was noted that there was an adjustment required from Receivables from non exchange transactions, mostly as a result of unrecognised unspent conditional grants. The reclassification is in relation to the provision for doubtful debts, which were previously included in the provision in relation to Receivables from exchange transactions..

[3] The adjustment that has been made to Property, plant and equipment is in relation to adjustments for the amounts on the reassessment of useful of the assets.

[4] The reclassification in the Payables to non - exchange transactions is in relation to Debtors with credit balances.

Statement of financial performance

Economic entity - 2021

	Note	As previously reported	Correction of error	Reclassification	Restated
Revenue from exchange transactions	19	10 676 573	(96 700)	(42 383)	10 537 490
Cost of Sales	20	(10 571 881)	121 389	-	(10 450 492)
Other income	21	1 022 924	(13 627)	42 383	1 051 680
Surplus for the year		**1 127 616**	**11 062**	**-**	**1 138 678**

The correction of error above resulted in the surplus for the year being restated from R54 609 to R65 383.

Controlling entity - 2021

	Note	As previously reported	Correction of error	Reclassification	Restated
Revenue from exchange transactions	19	10 650 931	(96 700)	(42 383)	10 511 848
Cost of Sales	20	(10 549 259)	121 389	-	(10 427 870)
Other income	21	1 022 924	(13 627)	42 383	1 051 680
Surplus for the year		**1 124 596**	**11 062**	**-**	**1 135 658**

The correction of error above resulted in the surplus for the year being restated from R55 160 to R66 245.

40. Segment information

General information

Identification of segments

The economic entity is organised and reports to management on the basis of nine major provinces within the country. The segments were organised around 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

Economic entity - 2022

	Laboratory Service	NIOH	NICD	SAVP	Total
Revenue					
Revenue from non-exchange transactions	262 518	92 465	285 074	-	640 057
Revenue from exchange transactions	11 536 725	17 925	29 264	13 694	11 597 608
Other income	392 856	449	7 468	-	400 773
Interest received	173 017	6 510	21 416	461	201 404
Fair value adjustment	-	-	-	1	1
Total segment revenue	**12 365 116**	**117 349**	**343 222**	**14 156**	**12 839 843**
Entity's revenue					**12 839 843**
Expenditure					
Cost of sales	9 325 266	118 789	345 299	18 247	9 807 601
Operating expenses	2 588 398	12 065	36 052	(1 521)	2 634 994
Depreciation and amortisation	264 087	10 354	39 216	169	313 826
Interest paid	8 454	42	48	-	8 544
Taxation	-	-	-	(1 553)	(1 553)
Total segment expenditure	**12 186 205**	**141 250**	**420 615**	**15 342**	**12 763 412**
Total segmental surplus					**76 431**

Economic entity - 2021

	Laboratory Service	NIOH	NICD	SAVP	Total
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 expenses	1 164 417	10 458	63 829	2 461	1 241 165
Depreciation and amortisation	82 390	5 218	13 371	(184)	100 795
Interest expense	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**

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.

41. Budget differences

Material differences between budget and actual amounts

The budget was prepared on an accruals basis covering the financial year ended 31 March 2022. The variances between budget and actual which are numerically 10% and R100m above or below budget are explained below:

41.1 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.

41.2 Grant Income

The grant income was more than anticipated during the budget.

41.3 Debt Impairment

The variance is due the growth in the amount over 90 days due from the provinces.

42. Going concern

The audited Annual Financial Statements have been prepared on the basis of accounting policies applicable to a going concern. This basis presumes that funds will be available to finance future operations and that the realisation of assets and settlement of liabilities, contingent obligations and commitments will occur in the ordinary course of business.

NHLS management has considered all the consequences of all current circumstances/events and conditions, and it has determined that they do not create a material uncertainty that casts significant doubt upon the entity's ability to continue as a going concern. Based on management assessment the NHLS will continue to operate as a going concern for the foreseeable future.

43. Events after the reporting date

NHLS continues to provide pathology services. The NHLS management reviewed all events that affected the NHLS after the reporting period, but before the financial statements for that period have been issued or are available to be issued. The following events and transactions occurred subsequent to 31 March 2022:

There are two litigation/possible litigation matters that were concluded after 31 March 2022.

Both these matters have had a positive outcome for the NHLS and have been included for disclosure under Note.33 as NHLS commitments.

A litigation matter regarding COVID-19 irregularities has received a judgement. Tthis matter has been disclosed under Note.34 as a contingent asset.

	Economic entity		Controlling entity	
	2022 R'000	2021 R'000	2022 R'000	2021 R'000

44. Fruitless and wasteful expenditure

Opening balance as previously reported	216	9	216	9
Opening balance as restated	**216**	**9**	**216**	**9**
Add: Expenditure identified - current	7 893	207	7 893	207
Less: Amounts recoverable - current	(6 618)	-	(6 618)	-
Closing balance	**1 491**	**216**	**1 491**	**216**

The amount shown as recoverable relates a penalty levied to the NHLS due to unforeseen event that was not within the control of entity. The NHLS is currently in a process to get the penalty waivered.

45. COVID-19 Donations

NHLS received the following donations in relation to the COVID-19 pandemic:

Donor Name	Items donated	2022 R'000	2021 R'000
ABSA Africa	Mobile Laboratory and Vehicles	-	5 100
Africa CDC	'2021: Reagents testing kits	-	-
Africa Union	'2022 - Lab Equipment '2021 - PPE / Reagents / Ventilators	24 456	-
Anglo American	'2021: Laboratory Equipment	-	-
Celtic Molecular Diagnostics		5	-
Chinese Government	Reagents and Laboratory Equipment	-	1 956
Department of Agriculture	Laboratory Equipment	-	1 400
Department of Water and Sanitation	PPE	-	2
Department of Health - (WC)	Laboratory Consumables	-	80
Ford SA	Surveillance Support	-	2 500
Google SA		-	-
International Atomic Energy Agency	'2021: PPE/Reagents/Laboratory Consumables	-	-
Kingdom of Netherlands	'2021: Laboratory Consumables	-	-
Right to Care	Lab Equipment	379	-
Russian Consulate	Reagents	-	-
Samsung Electronics (SA) Pty) Ltd	Reagents	-	2
Sasol	Mobile Laboratory Vehicles Fuel	-	241
Sasol Foundation	'2021: Mobile Laboratory Vehicles	-	-
Solidarity	'2022 - COVID-19 Call Cen-tre Funding 2021 - Reagents	17 428	250 869
Technical University of Denmark		6 733	-
The Foundation for Professional Development (German)	Laboratory Equipment	-	10 745
Total SA	Reagents	-	9 000
UNICEF	'2021: Reagents / Laboratory Consumables	-	-
US Defence Threat Reduction Agency	Laboratory Equipment	-	460
Volkswagen SA	Laboratory, Office and Computer Equipment	-	4 000
World Health Organisation	Reagents / LaboratoryConsumables	-	11 536
		49 001	**297 891**

The amounts shown above from the donors are in South African Rands and the monetary 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	
		2022 '000	2021 Restated* '000	2022 '000	2021 Restated* '000
Revenue					
Sale of goods		13 694	25 642	-	-
Rendering of services		11 583 914	9 752 964	11 583 914	9 752 964
Government grants & subsidies		640 057	758 884	640 057	758 884
		12 237 665	**10 537 490**	**12 223 971**	**10 511 848**
Cost of sales	20	**(10 117 395)**	**(10 450 491)**	**(10 099 073)**	**(10 427 869)**
Gross surplus		**2 120 270**	**86 999**	**2 124 898**	**83 979**
Other income					
Fair value adjustments: Notional interest		8 107	42 383	8 107	42 383
Fees earned		1 569	2 284	1 569	2 284
Royalties received		2 095	2 063	2 095	2 063
Discount received		1 365	305	1 365	305
Recoveries		59 484	502 922	59 484	502 922
Teaching Income		87 066	87 532	87 066	87 532
Sundry Income		833	826	833	826
Grant income recognised		188 855	162 496	188 855	162 496
Interest received	23	201 404	163 705	200 943	163 186
Public contributions and donations		49 000	250 869	49 000	250 869
Exchange gains		2 399	-	2 399	-
Grant assets fair value adjustments		1	15	-	-
		602 178	**1 215 400**	**601 716**	**1 214 866**
Expenses (Refer to page 86)		**(2 639 023)**	**(1 232 839)**	**(2 640 447)**	**(1 228 903)**
Operating surplus	22	**83 425**	**69 560**	**86 167**	**69 942**
Interest expense	24	(8 546)	(3 697)	(8 546)	(3 697)
Surplus before taxation		**74 879**	**65 863**	**77 621**	**66 245**
Taxation	25	(1 553)	480	-	-
Surplus for the year		**76 432**	**65 383**	**77 621**	**66 245**

DETAILED STATEMENT OF FINANCIAL PERFORMANCE (continued)

	Note(s)	Economic entity		Controlling entity	
		2022 '000	2021 Restated* '000	2022 '000	2021 Restated* '000
Operating expenses (by function)					
Advertising		543	889	543	895
Archiving and Storage		9 393	8 497	9 393	8 497
Auditors remuneration	28	8 710	12 511	8 710	12 511
Bad debts written off		2 139	1 640	2 139	1 640
Bank charges		13 217	9 766	13 172	9 725
Cleaning		3 293	8 107	3 293	8 094
Computer expenses		1 457	2 415	1 418	2 414
Conferences and seminars		564	56	545	56
Consulting and professional fees		48 918	67 873	48 674	67 717
Consumables		17 893	18 335	17 839	18 303
Debt Impairment		1 227 658	32 654	1 231 130	30 559
Debt collection		923	952	923	952
Delivery expenses		2 420	2 817	2 421	2 806
Depreciation, amortisation and impairments		4 036	(8 315)	3 938	(8 429)
Discount allowed		37 541	35 674	37 541	35 674
Employee costs		483 089	299 341	481 960	298 476
Entertainment		-	2	-	2
Fines and penalties		-	(27)	-	(27)
Insurance		9 306	9 173	9 306	9 173
Lease rentals on operating lease		36 304	41 000	36 262	40 875
Legal expenses		39 729	20 494	39 729	20 492
Loss on disposal of assets		4 283	3 335	4 283	3 335
Loss on exchange differences		-	2 127	-	2 127
Minor assets		5 092	8 929	5 092	8 929
Motor vehicle expenses		1 198	11 093	1 198	11 093
Other contract expenses		3	-	3	-
Other expenses		12	896	13	895
Packaging		10 457	9 552	10 338	9 407
Petrol and oil		17 946	10 447	17 946	10 447
Printing and stationery		55 203	44 624	55 181	44 585
Postage and courier		604	329	604	329
Project Management expenses		13	690	13	690
Promotions		40	2	40	2
Promotions and sponsorships		33	38	33	38
Repairs and maintenance		38 006	48 442	37 986	48 412
Research Trust		93	5	93	5
Royalties and license fees		1 607	1 582	1 607	1 582
Security		1 023	4 559	1 023	4 559
Software development expenses		19 557	15 546	19 557	15 546
Software expenses		178 967	176 177	178 950	176 177
Staff welfare		6 129	6 078	6 064	5 911
Subscriptions		4 137	4 763	4 078	4 740
Telephone and fax		90 944	124 541	90 876	124 459
Training		40 661	26 077	40 661	26 077
Travel - local		18 677	11 412	18 667	11 412
Travel - overseas		15	24	15	24
Utilities		197 190	157 717	197 190	157 717
		2 639 023	**1 232 839**	**2 640 447**	**1 228 903**

**** See Note 39***

The supplementary information presented does not form part of the audited group annual financial statements and is unaudited

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