STANDARD OPERATING PROCEDURE

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GLOSSARY/ABBREVIATIONS

APTT	Activated partial thromboplastin time
βHCG	Beta- Human chorionic gonadotropin
CD	Cluster designation
CEA	Carcinoembryonic antigen
CK-MB Mass	Creatine Kinase-myocardial band Mass
CPD	Continual Professional Development
CRP	C-Reactive Protein
CrAg LFA	Cryptococcal antigen lateral flow assay
CV	Coefficient of variation
ESR	Erythrocyte sedimentation rate
FSH	Follicle stimulating hormone
HBsAg	Hepatitis B surface Antigen
HIV	Human Immunodeficiency Virus
IEC	International Electrotechnical Commission
IFA	Immunofluorescence assay
INR	International normalised ratio
ISO	International Organisation for Standardisation
IUATLD	International Union Against Tuberculosis and Lung Disease
KZN	Kwazulu-Natal
LFA	Lateral Flow Assay
LH	Luteinizing hormone
NHLS	National Health Laboratory Service
NICD	National Institute for Communicable Diseases
NIOH	National Institute for Occupational Health
PCO2	Partial pressure carbon dioxide
PO2	Partial pressure oxygen
POCT	Point of Care Testing
PSA	Prostate specific antigen
PT	Proficiency Testing
PT	Prothrombin time
PTS	Proficiency Testing Scheme
QAD	Quality Assurance Division
RPR	Rapid plasma reagin
SAIMR	South African Institute for Medical Research
SD	Standard deviation
SDI / z-score	Standard deviation index (z-score)
SMLTSA	Society of Medical Laboratory Technologists of South Africa
SOP	Standard operating procedure
T3	Total triodithyronine test
T4	Total thyroxine test
TB	Tuberculosis (Mycobacterium)
TPHA	Treponema pallidum haemagglutination assay
TSH	Thyroid stimulating hormone

1. INTRODUCTION

The National Health Laboratory Service (NHLS) was formed in 2001. The NHLS comprises of former South African Institute for Medical Research (SAIMR), the National Institute for Communicable Diseases (NICD), the National Institute for Occupational Health (NIOH) and the former state laboratory services, which between them have provided both a research and diagnostic laboratory service for the public sector in South Africa since 1912. The Kwazulu-Natal (KZN) provincial laboratories were incorporated into the NHLS on 01 October 2006.

Part of the function of the NHLS Quality Assurance Division (QAD) is to provide Proficiency Testing schemes (PTS) for all laboratory specialties. These schemes, are under continuous review and are designed to be technically relevant, currently covers Bacteriology, Biochemistry, Flow Cytometry, Haematology, Serology (Syphilis, Hepatitis and HIV), Parasitology, Molecular Biology, Mycobacteriology, and Mycology.

NHLS QAD provides these PT schemes to all NHLS laboratories in South Africa and laboratories in over 20 countries throughout Africa. The QA Division also co-ordinates and advises on the use of international Quality Assessment Programmes for specialist assays, and has the responsibility for monitoring the quality of service provided by the NHLS laboratories.

The Schemes complies with requirements of ISO/IEC 17043:2010. The list of accredited schemes is available on the SANAS website under accreditation number PTS0005: -

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The PT Schemes run by the NHLS have been designed with a specific purpose in mind, namely, to measure laboratory performance against established (and best practice) criteria. In order to achieve the highest levels of objectivity, the management of these PT Schemes is carried out by the Quality Assurance Division, Sandringham, Johannesburg which is entirely independent of the core service functions of the NHLS with a line function that reports directly from the NHLS Academic Affairs, Research and QA Executive Manager to the NHLS Chief Executive Officer. As a consequence of this structure, the risk of collusion between participants is mitigated, and a level of objectivity is maintained.

Accreditation of the PT Schemes infers parity with similar international PT Schemes. In order to achieve this accreditation, many stringent technical requirements must be satisfied, which includes integrity of data, accuracy of results, and preservation of the confidential nature of participant results.

2. RESULTS (All Schemes)

Participants may send results by electronic system. facsimile or email, before the nominated closing date.

As most of the PT Schemes statistically analyse participant performance by comparing individual results to a consensus of the mean (ISO/IEC 17043:2010), results received after the closing date (and thus after the calculation of the statistical mean) cannot be processed.

Results submitted to an incorrect fax number or email address will also not be accepted.

3. REPORTS (All Schemes)

Participant results are analysed and distributed before the next survey. Reports are printed and posted to participants. The delivery of these reports is by courier.

4. WEB PTS Enrollment

The NHLS Proficiency Testing Schemes (PTS) has an automated enrolment process. Use this link to access the enrolment page: http://webpts.nhls.ac.za.
All laboratories need to enroll their individual PTS's through this portal. Participation fees are levied for applicants external to NHLS laboratories.

For requests, queries or access to the website, please contact the NHLS PTS Department on ptsadmin@nhls.ac.za.

5. CHEMICAL PATHOLOGY

5.1 General chemistry

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Twenty-seven parameters are analysed in twelve monthly samples. Analytes covered are sodium, potassium, carbon dioxide, chloride, magnesium, urea, creatinine, total protein, albumin, calcium, phosphate, cholesterol, glucose, uric acid, total bilirubin, direct bilirubin, triglycerides, alkaline phosphatase, aspartate transaminase, alanine transaminase, lactate dehydrogenase, gamma glutamyl transferase, amylase, creatine kinase, lipase, iron lactate, high density lipoprotein and lithium. The complete set of material is mailed at the beginning of the year together with instructions and result forms.
A confidential performance report is issued on a monthly basis to participating laboratories. The information is provided:

a) The overall mean and standard deviation (SD) and CV for each analyte for all methods. Results outside 2SD are starred and those in excess of 3SD are flagged as wild.
b) The method mean, SD and CV for specific methodologies.
c) The *z*-score, a measurement of bias relative to the overall mean.

5.2 Therapeutic Drugs

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Six rounds per year are conducted bimonthly. Analytes covered include: acetaminophen, carbamezepine, digoxin, , phenobarbitone, phenytoin, salicylate, theophylline, valproic acid and the antibiotics: amikacin, gentamycin and vancomycin. Results are compared against target values for specific systems with acceptable limits derived from Rhoads (Data Innovations).

5.3 Blood Gases

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Six rounds per year are conducted bimonthly. The assays assessed are pH, partial pressure carbon dioxide (pCO_2) and partial pressure oxygen (pO_2) at two levels per survey. Results are compared against target values for specific systems with acceptable limits derived from Rhoads (Data Innovations).

5.4 Endocrinology

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Six rounds per year are conducted bimonthly. Analytes covered are α-foetoprotein, Carcinoembryonic antigen (CEA), cortisol, Beta- Human chorionic gonadotropin (βHCG), free total triodithyronine test (T3), free total thyroxine test (T4), follicle stimulating hormone (FSH), Luteinizing hormone (LH), oestradiol, progesterone, prolactin, prostate specific antigen (PSA), testosterone, and thyroid stimulating hormone (TSH). Results are compared against target values for specific systems with acceptable limits derived from Rhoads (Data Innovations).

5.5 Cardiac **Markers** (CKMB Mass, Trop I and Trop T)

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Four parameters are tested six times a year. Analytes covered include: Creatine Kinase-myocardial band Mass (CK-MB Mass), Troponin I, Troponin T and Troponin T for Point of Care Testing (POCT- Cobas h232). Results are compared against target values for specific systems with acceptable limits derived from Rhoads (Data Innovations). The complete set of material is sent once a year together with instructions and results forms.

5.6 C-Reactive Protein (CRP)

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The CRP PTS is performed four times a year. CRP is the only analyte tested under this PTS. The complete set of material is sent out to participants once a year together with instructions and results forms. A confidential performance report is sent to participating laboratories. The information is provided:

a) The overall mean and standard deviation (SD) and CV for each analyte for all methods. Results outside 2SD are starred and those in excess of 3SD are flagged as wild.
b) The method mean SD and CV for specific methodologies.
c) The *z*-score, a measurement of bias relative to the overall mean.

5.7 Beta- Human chorionic gonadotropin (BhCG)

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Two samples are sent four times a year. The samples are shipped in the month it is due, the participant instructions are sent once a year together with the result sheet. A confidential report is sent to participating laboratories the information provided is:

a) Participant results compared to the expected results, as well as the evaluating the performance as acceptable or non-acceptable.
b) A graph indicating the acceptable and non-acceptable performance of the participating laboratories.

6. HAEMATOLOGY

6.1 Full blood count and Platelets

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Twelve rounds a year (one per month) are sent out. One stabilized human whole blood samples are provided for the determination of white and red cell counts, haemoglobin, haematocrit, mean cell volume and platelets.

A confidential performance report is issued on a monthly basis to participating laboratories. The following information is provided:

a) The overall mean and standard deviation (SD) and CV for each test parameter for all methods. Results outside 2SD are flagged.
b) The method mean, SD and CV for specific methodologies.
c) The *z*-score, a measurement of bias relative to the overall mean.

6.2 Morphology peripheral blood smear

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Twelve rounds a year (one per month) are sent out. One stained blood film for differential cell counts, morphology and interpretative comments. Feedback is given

on the laboratory performance as well as all laboratory results relevant to the work-up of each slide presentation. These are used by the participants for reference purposes.

6.3 Manual reticulocyte count

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Three rounds (minimum) a year are sent to participants. One stained blood film is provided for the manual determination of reticulocyte counts. Feedback is given on the laboratory performance as well as all laboratory results relevant to the work-up of each slide presentation. These are used by the participants for reference purposes.

6.4 Erythrocyte sedimentation rate (ESR)

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Four rounds per annum are sent to participants. One stabilised human whole blood sample is provided for the determination of ESR. Participant performance is measured against the Consensus of the Mean.

6.5 D-Dimer

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Specimens are distributed to participating laboratories four times per cycle**.**
The D-Dimer scheme issues two samples of lyophilized plasma in which participants are required to determine the D-Dimer levels within the preparation.
Each laboratory performance report includes the performance of all laboratories (all technologies). The report includes the following:

a) Results of survey number and sample A and sample B.
b) A D-Dimer results verification sheet that summarises the information submitted by the participant and identifies the institution, laboratory participant number, instrument, serial number and method used.
c) A summary table of statistics that includes: reported value (laboratory submitted result), aggregate group mean value (method mean), residual, SD, %CV and SDI (z-score).
d) A cumulative SDI (z-score) graphical representation of performance, which illustrates the laboratory's SDI (z-score) value, within the group distribution.

6.6 Automated Differential Count

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Specimens are distributed to participating laboratories four times per cycle**.** The automated differential count scheme issues one stabilised human whole blood sample for the determination of white blood cell, the percentage and absolute count results for neutrophils, lymphocytes, monocytes, eosinophils and basophils.
Each laboratory performance report includes the performance of all laboratories (all technologies). The report includes the following:

a) Results of survey and sample number.
b) An automated differential count results verification sheet that summarises the information submitted by the participant and identifies the institution, laboratory participant number, instrument, serial number and method used.
c) A summary table of statistics that includes: reported value (laboratory submitted result), aggregate group mean value (method mean), residual, SD, %CV and SDI (z-score). This includes all methods and specific methods.
d) A cumulative SDI (z-score) graphical representation of performance, which illustrates the laboratory's SDI (z-score) value, within the group distribution.

6.7 Coagulation (PT, INR, APTT)

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Specimens are distributed to laboratories participating in the coagulation scheme.

- Sample type- two levels lyophilised samples.
- Volume- 1ml when reconstituted with redistilled water.
- Parameters- PT and APTT

Participants are required to process the PT samples following their standard operation procedure for coagulation.

Each laboratory receives an individual confidential report.
The report include the following.

- The overall mean, standard deviation (SD), coefficient of variation (CV) for each parameter tested.
- The mean, standard deviation and coefficient of variation for specific methodologies.
- Results outside the 2SD will be flagged.
- The Z-score a measurement of bias relative to the overall mean.

7. MICROBIOLOGY

7.1 Bacteriology (general)

Scheme Manager: Zazi Molebatsi
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Rounds are issued three times per year. Each round consists of 4 challenges: specimens A-D. Isolates are selected to cover one or more of the following challenges: bacteriological identification, antimicrobial susceptibility testing and

clinical relevancy. The paper challenge tests the laboratory's response to pre-and post-analytical situations.

The material supplied consists of lyophilised cultures, simulated specimens, microscopic preparations, general instructions and laboratory response forms. 10-20% of the prepared samples are retained for weekly quality control. This is to check for organism viability until the closure of the round.

Participants are evaluated on relevant aspects of laboratory processing, including microscopy, culture and identification, antimicrobial susceptibility testing and reporting. The capabilities of laboratories are taken into account in evaluation of responses (academic, regional or peripheral).

Each laboratory receives an individual report and analysis of their performance; a commentary with a review of overall laboratory performance, a teaching exercise on a relevant aspect of laboratory performance and if necessary a corrective action form.

7.2 Mycobacteriology

7.2.1 Mycobacteriology Microscopy

Scheme Manager: Esther Tsheola
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Rounds are issued three times per year and consist of a panel of ten unstained slides. The slides are stained by the participant with a method of their choice. Laboratories are requested to examine the slides and grade the results according to the International Union Against Tuberculosis and Lung Disease (IUATLD).

7.2.2 Mycobacteriology Culture

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Mycobacteriology culture rounds are issued three times a year. Each round consists of four specimens for culture; participants are expected to conduct Ziehl Neelson (ZN) stain, Mycobacterium Tuberculosis Complex, (MTBC) Antigen Test identification and/or susceptibility testing. Laboratories are graded on the accuracy of their ZN stain, Mycobacterium Tuberculosis Complex (MTBC) Antigen Test, identification and susceptibility result. Each laboratory receives an individual report with their results and score.

7.2.3 Mycobacteriology Line Probe Assay

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Mycobacteriology Line Probe Assay (LPA) PTS is distributed three times a year. The panels consist of five samples which contain heat inactivated of MGIT cultures. Isolates are selected to cover various identification and drug susceptibility profiles. Participants are evaluated on band appearance, appropriate band patterns on the original LPA strips or Genoscan results and categorization of drug susceptibility findings for the two drugs of the assay. Each participant receives an individual report that details analysis of their performance and overall performance of participating laboratories.

7.3 Mycology

7.3.1 Yeasts/-Basic/ Advanced/-Mycology

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Three rounds per year are conducted. The Basic Mycology PT Scheme tests the laboratory's proficiency at detecting the presence or absence of fungal elements on microscopy and basic identification of yeast isolates. All laboratories that perform bacteriology should have proficiency in these aspects of mycology.

The Basic Mycology PT Scheme consists of two specimens.

a) One is a slide for staining and microscopy.
b) The other is either lyophilized cultures or cultures suspended in distilled water, for culture and identification.

The Advanced Mycology PT Scheme is intended for those laboratories that routinely process specimens for mycology culture and identification.

The Advanced Mycology PT Scheme consists of three specimens.

a) One is a slide for staining and microscopy.
b) The other is either lyophilized cultures or cultures suspended in distilled water, for culture and identification.
c) The other is either lyophilized cultures or cultures suspended in distilled water, for culture, identification and susceptibility.

Participants are required to identify the organisms up to the level that they would normally go with clinical specimens. A confidential performance report containing the correct identification, the optimized procedure and comments on significance is issued to participants.

7.3.2 Moulds

Scheme Manager: Thokozile Zulu
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Tel: +27 (0)11 555-0563
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Three rounds per year are conducted, consisting of either lyophilised cultures or cultures suspended in distilled water.

Four specimens are sent in each round.

a) Three of the four specimens are marked.

b) The fourth specimen is a bonus isolate. This allows for the less common organisms to be included in the PT Scheme. It serves as a teaching exercise and as a challenge for those laboratories that are proficient in mycology.

Participants are required to identify the organisms up to the level that they would normally go with clinical specimens. A confidential performance report containing the correct identification, the optimised procedure and comments on significance are issued to participants.

7.4 Parasitology

7.4.1 Stool Parasites

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Fax: +27 (0)86 225 2460

Three rounds are sent out a year, each comprising ±5 challenges. Round challenges encompass parasite identification and laboratory techniques (such as staining). A teaching series is included in every round to encourage participants to learn more about medically important parasites.

7.4.2 Blood Parasites

Scheme Manager: Zazi Molebatsi
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Three rounds are sent out a year, each comprising ±5 challenges. Round challenges encompass parasite identification and laboratory techniques (such as staining). A teaching series is included in every round to encourage participants to learn more about medically important parasites.

7.4.3 Malaria RDT

Three rounds are sent out a year, each comprising 2 simulated blood challenges. Laboratories are requested to perform malaria rapid testing on these specimens. Laboratories are graded qualitatively for this programme.

7.5 Serology

7.5.1 Non-Specific Treponemal Syphilis Serology

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This PT Scheme is issued three times per year. Rounds consist of 3 serum specimens. Laboratories are requested to perform non-treponemal syphilis testing on these specimens and to record the titre if specimens are positive. Grading of the laboratories is two-fold being both qualitative and quantitative. Laboratories are issued with reports detailing their performance compared with other laboratories using the same test kit.

7.5.2 Specific Treponemal Syphilis Serology

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This PT Scheme is also issued three times per year. Rounds consist of 3 serum specimens. Laboratories are requested to perform treponemal syphilis testing on these specimens. Laboratories are graded qualitatively for this programme only. Laboratories are issued with reports detailing their performance compared with that of all the laboratories as a whole.

7.5.3 Human Immunodeficient Virus (HIV) Serology

Scheme Manager: Mahlatse Maleka
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Three rounds are conducted per year using stabilized human serum with six samples per round. Sample pools are evaluated against a selection of routinely used HIV test kits before distribution to participants. Participant results must be returned to the HIV Serology Scheme Manager.

7.5.4 Hepatitis B surface Antigen (HBsAg) Serology

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Three rounds are conducted per year using stabilized human serum with six samples per round. Sample pools are evaluated against a selection of routinely used HBsAg test kits before distribution to participants. Participant results must be returned to the HBsAg Serology Scheme Manager.

7.6 Molecular Biology

7.6.1. Early Infant Diagnosis (EID) of HIV

Scheme Manager: Mahlatse Maleka
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It is a qualitative PT Scheme which is issued twice a year. Each HIV EID panel consists of five dried blood spots (DBS). Two identical sets of PTS panels are sent per shipment. Ten HIV positive control DBS and ten HIV negative DBS are also provided to participants. Laboratories are issued with reports detailing their individual performance as compared to other laboratories as a whole.

7.6.2. Viral Load

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It is a quantitative PT Scheme which is issued twice a year. Each HIVVL panel consists of five dried tube specimens (DTS). Two identical sets of PTS panels are sent per shipment. Laboratories are issued with reports detailing their individual performance as compared to other laboratories as a whole.

8. FLOW CYTOMETRY (CD4 / T-Cell monitoring)

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The Immune Monitoring scheme issues stabilised whole blood which participants are required to determine the lymphocyte subsets (cluster designation-CD) within the preparation. The following markers are offered:

- CD4+ Absolute count
- CD4+ (CD3+CD4+) Absolute count
- CD3+CD8+Absolute count
- CD3+Absolute count
- CD4+ Lymphocyte percentage
- CD4+ (CD3+CD4+) Lymphocyte percentage
- CD3+CD8+ Lymphocyte percentage
- CD3+ Lymphocyte percentage
- $CD19^{+}$ B cells Absolute count
- $CD3^{-}/CD16^{+}/CD56^{+}$ Natural killer cells Absolute count
- $CD19^{+}$ B cells Lymphocyte percentage
- $CD3^{-}/CD16^{+}/CD56^{+}$ Natural killer cells Lymphocyte percentage

a) Each laboratory performance report includes the performance of all laboratories (all technologies). The report includes the following:
b) Results of survey number, trial number and sample A and sample B
c) An immunophenotyping results verification sheet that summarises the information submitted by the participant and identifies the institution, laboratory participant number, the lysing protocol, flow cytometer, serial number, monoclonal antibody panel, and phenotyping results.
d) A summary table of statistics that includes: reported value (laboratory submitted result), aggregate group mean value (method mean), residual, SD, %CV and SDI (z-score).

e) A cumulative SDI (z-score) graphical representation of performance, which illustrates the laboratory's SDI (z-score) value, within the group distribution.

Specimens are distributed to participating laboratories six times or three times per cycle.

9. CRYPTOCOCCAL ANTIGEN LATERAL FLOW ASSAY CrAg LFA)

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Specimens are distributed to participating laboratories six times or three times per cycle.
Three simulated samples are sent per survey.
Laboratories are graded qualitatively for this scheme. Laboratories are issued with reports detailing their performance compared with that of all the laboratories as a whole.

10. Backup PT Scheme Managers

a) Celeste McPherson

Beta hCG, CD4, CRP and D-Dimer

b) Bongiwe Mofokeng

Automated Differential count, Cardiac, Chemistry (General), Morphology, Endocrine

c) Hazel Aggett

Blood Gas, Coagulation (PT, INR, APTT), ESR and Full Blood Count, Therapeutic Drug Monitoring

d) Esther Tsheola

Bacteriology, Cryptococcal Antigen, HIV Viral Load and Mycology Moulds

e) Mahlatse Maleka

Malaria RDT, nonspecific Treponemal serology (e.g. Syphilis RPR) and specific Treponemal serology (e.g. Syphilis TPHA)

f) Thokozile Zulu

Hepatitis B surface antigens, HIV Serology, Mycology Yeast and Parasitology (Blood)

g) Zazi Molebatsi

HIV Early Infant Diagnosis, Parasitology (Stool), TB Culture, TB LPA and TB Microscopy

11. APPEALS

Please direct all appeals regarding scoring/ evaluation of your performance to the relevant Proficiency Scheme Manager using the contact details published in this document.

12. COMPLAINTS/ FEEDBACK

We value your feedback. Please direct your comments and suggestions to:

Ms Patience Dabula
National Quality Assurance Manager
NHLS
Private Bag X8
Sandringham
2131
South Africa
Phone: +27 (0)11 386-6151/6147
e-mail: patience.dabula@nhls.ac.za

Acknowledgement of Reading Form

Title: PTS Handbook

My signature confirms that I have read and understood the content of this document and relevant kit insert (where applicable).

Name	Signature	Date

Note to the Quality Rep: - This form must be filed for 5 years to provide audit traceability.