

PRL Resource Management Manual			
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Personnel

1.0. Purpose

This SOP gives guidance on the structure, personnel policies and how personnel records are managed at Proteus Laboratories.

2.0. Scope

This applies to all laboratory staffs including formal staffs, students and support staff in Proteus laboratories.

3.0. Abbreviations and Definitions

SOP Standard operating procedure

QMS Quality Management System

SO Safety Officer

QO Quality Officer

N/A Not Applicable

4.0. Responsibilities

TASKS	RESPONSIBLE	ACCOUNTABLE
Making organization plan, ensuring personnel policies are in place	Lab manager	Laboratory director

5.0. Procedure

5.1. Personnel Qualifications

The Laboratory management documents all personnel qualifications for each position from lab management, quality officer and respective lab personnel in their respective job descriptions. The qualifications reflect the appropriate education, and experience that is appropriate to the tasks performed.

The personnel making judgments with reference to examinations are qualified medical technologists. Staff job descriptions are maintained in their personnel files.

5.2. Personnel Files

5.2.1 Maintenance of Personnel records

The following are the minimum records to be maintained in personnel files;

- **Job description**
- **Education and professional qualifications**
- **Copy of Certification or License**
- **Work experience / CV**
- **Introduction of new staff to the laboratory environment**
- **Training and Competency assessments**
- **Records of continuing education and achievement**
- **Review of staff performance**
- **Reports of accidents and exposure to occupational hazards.**
- **Immunization status.**

The personnel records are confidential and are only accessed by the quality / Laboratory manager or any authorized person. The files are kept in a lockable cabinet in the laboratory manager's office and reviewed annually or when needs arises and reviewing is done by the Laboratory Manager or Laboratory Director.

The personnel files for those who resigned or terminated the contract of services with Proteus laboratories, are archived for at least 5 years.

5.3 Personnel Induction to the organisational environment

All new staff are taken through Orientation programme. The orientation programme covers:

- Organizational policies
- Quality management system
- Department / section of the lab the employee will be working in
- Applicable Laboratory information system
- Health and safety
- Ethics
- Confidentiality of patient information

Induction / orientation training should be completed within a month of joining the organisation.

The Quality Management System

Laboratory staff undergo both initial and refresher trainings on LQMS. The trainings are conducted by qualified trained staff. Personnel who have been trained externally (via organized workshops) qualify to train the other Laboratory staff on site.

Assigned work processes and procedures

- a) All new staff is trained on work specific procedures prior to running patients' samples on their own.

- b) All personnel performing work processes and procedures, or testing receive remedial training if need be after competency assessment or other indicators demonstrate the

laboratory personnel is not competent in the performance of the same procedure. Remedial training is done in accordance with the specific work processes and procedures or testing. Work processes and procedures testing is not permitted until all training is successfully completed, including competency assessment.

- c) The Laboratory Manager / designate is responsible for training new staff in the laboratory.
- d) For testing/analytical processes, the training covers pre-examination, examination and post-examination aspects, observing the trainer perform the procedure and then having the trainer observe the trainee performing procedure.

Health and Safety training

All laboratory personnel undergo training on health and safety to ensure prevention or containment of the effects.

The safety officer or designee is responsible for organizing and conducting the health and safety training. Safety audit is conducted annually, and fire drills are done annually as well.

Laboratory information management system

A Training is organised where staff are trained on the use of the information management system in the laboratory. A competent staff on information management system conducts the training.

Personnel training on ethics and confidentiality of patient information

All laboratory staff are trained on ethics and confidentiality and taken through the applicable ethical codes of conducts pertaining laboratory work.

Provision of a continuous education programme

When a need arises in the Laboratory to refresh personnel both in the laboratory and the laboratory clients, A CME is conducted, and information is provided. Evidence of the CME is by attendance list and in some cases, a report or handouts are provided. Online journals are accessible to lab staff via the lab internet.

On the job training

All employees receive “on-the-job” training by the responsible assigned competent personnel. New staff are trained before working in the sections assigned.

After a probation period, all new/transferred employees are evaluated against the position requirements and if performance is found to be satisfactory, the applicable position is awarded. Upon completion of initial training, all personnel performing analysis are required to prove competence prior to analysing patient samples.

All laboratory staff members are to undergo training in several procedures, policies and practices upon entry of employment and during their career with Proteus Laboratories.

All personnel undergoing training are supervised by competent laboratory staff.

The effectiveness of the training program is reviewed annually.

The training process for technical procedures such as laboratory testing consists of the following steps:

- Trainee reads the laboratory procedures, work instructions, or other applicable documents.
- trainee observes demonstration of the procedure by a trainer.
- Trainee performs the procedure under observation by a trainer.

When a Staff has persistently deviated from the set procedures a training need will be identified, and the laboratory manager assigns some competent lab personnel to carry out the training.

5.5 Conducting Initial and Refresher trainings.

The laboratory ensures that laboratory personnel are trained and competent at all times, where by in case of change or modification of a test or change of personnel leading to out of touch with the previous technique, the lab personnel is offered a refresher training followed by competency testing respectively. Trainings are conducted both Internally and Externally according to training needs.

6.0 COMPETENCE ASSESSMENT

6.1 Assessment of competence of personnel to perform assigned managerial or technical tasks

Following appropriate training, the laboratory assesses the competence of each person to perform assigned managerial or technical tasks according to the established criteria.

Laboratory staff is assessed by using a combination of the following approaches:

- Direct observation of routine work processes and procedures, including all applicable safety practices
- Direct observation of equipment maintenance and function checks
- Monitoring the recording and reporting of examination results
- Review of work records
- Assessment of problem-solving skills
- Examination of specially provided samples such as previously examined samples, interlaboratory comparison materials or split samples.

6.2 Initial Competency assessments

1. Initial competency is performed after initial training on how to carry out a specific task and is considered successful when a set competence criteria is full filled for that task, (for example it can be accomplished by performing an unobserved run with three blind samples and obtaining a 100% score. A competency assessment

is appropriately completed each time competency assessment is performed on a laboratory personnel.

2. Initial competency is also performed by designated persons prior to a new methodology being implemented. Initial competency for new tests/methods/procedures are performed during the assay/procedure validation stage whenever possible.

6.3 Reassessment of competence

Retraining is done when there is change in a method or when the employee has demonstrated failure to perform the procedure. Competence assessment is continual through reviewing of staff records of IQC, EQA and Equipment maintenance among others.

Reviews of staff performance

The laboratory ensures that the review of staff performance considers the need of the laboratory and of the individual in order to maintain and improve the quality of service given to the user and encourage productive working relationship. Staff performance reviews are done daily by the lab manager / lab director reviewing the work performed.

Orientation Plan

Areas to be Covered	Comments	Completed	
		Yes	No
Introduction to dept			
Introduction to Organisation			
Laboratory Safety Rules			
QMS			
Lab Information System			
Training in the department			
Confidentiality contract			
Ethics			
Emergency Procedures			
Personal Protective Equipment (PPE)			
Personnel contract and Job description			

Employee Name: -----

Supervisor's Signature: -----

Date: -----

9.0. References

ISO 15189 201

5.3 Equipment

1.0 Purpose

This SOP specifies the schedule and requirements for calibration, frequency, performance verification, and maintenance of laboratory testing instruments and equipment in order to ensure that the results from the equipment are accurate, precise and reproducible.

2.0 Scope

This SOP applies to all laboratory personnel.

3.0 Terms, Definitions and Abbreviations

3.1 Terms and Definitions

Calibration—Adjustment or standardization of the accuracy of a measuring instrument by comparison with a certified reference or standard.

Certified Reference Material (CRM)—Reference material whose property values are certified by a technically valid procedure and accompanied by or traceable to a certificate or documentation issued by a certifying organization.

Laboratory Equipment— Analytical instrumentation and equipment affecting the accuracy or precision of a test method.

Performance Verification—The confirmation of the reliability of a previously validated method(s) or equipment.

Quality Control Checks—Periodic confirmation of the reliability of equipment, instrumentation, and/or reagents.

Reference Standard —Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Traceability–The linking of measurement standards and/or measuring instruments to relevant national or international standards, through an unbroken chain of comparisons.

3.2 Abbreviations

BIPM - International Bureau of weights and measures

CIPM - International Committee of weights and measures

CMC - Calibration and measurement capabilities

ILAC - International Laboratory Accreditation Cooperation

ISO – International Organisation Standards

KCDB- Key Comparison Database

NIST - National Institute of Standards and Technology

SANAS - South Africa National Accreditation Services

7.0 Procedures

Calibration is done according to equipment specific calibration procedure as defined by the manufacturer or laboratory

7.1 Calibration interval

All equipment in the laboratory are calibrated as determined by the manufacturer of the specific equipment.

7.1.1 Automatic pipettes

- Parameter to be calibrated: Volumes.
- **Procedure:** Involves measuring predetermined volumes and comparing the volumes obtained.

7.1.2 Timers

- **Parameter to be calibrated:** Predetermined time intervals
- **Procedure:** Standard time clock is used to compare the same predetermined timing with the timer under calibration.

7.1.3 Centrifuges

- **Parameter to be calibrated:** Speed of rotation.

- **Procedure:** A tachometer is to compare the speed with the displayed speed by the centrifuge.

7.1.5 Thermometers

- **Parameter to be calibrated:** Temperature.
- **Reference Material** Precision thermometers are used to give the correct value according to a pre-set sequence

7.1.6 Chemistry Analysers

- **Parameter to be calibrated:** Targeted Values
- **Procedure:** Run the calibrators as per manufacturer's instructions and compare the obtained values with the predetermined values.

7.1.7 FBC Analysers

- **Parameter to be calibrated:** Targeted Values
- **Procedure:** Run the calibrators as per manufacturer's instructions and compare the obtained values with the predetermined values.

7.1.8 CD4 Analyser

- **Parameter to be calibrated:** Targeted Values
- **Procedure:** Run the calibrators as per manufacturer's instructions and compare the obtained values with the predetermined values.

7.2 Equipment calibration and verification

The Laboratory accepts calibrations that have metrological traceability i.e.

- Calibration certificates and reports issued by calibration laboratories;
- certificates issued by laboratories accredited by full members of the ILAC arrangement;
- calibration certificates issued by the National Metrology Institute of South Africa (NMISA); and
- Calibration certificates issued by members of the International Committee of Weights and Measures (CIPM) arrangement, whose Calibration and Measurement Capabilities (CMC's) are accepted into the International Bureau of Weights and Measures (BIPM) Key Comparison Database (KCDB).

Service engineers perform equipment calibration for equipment such as centrifuges, analysers while laboratory personnel perform calibration of auxiliary instruments like timers, thermometers and pipettes. Manufacturer operating manuals are used to determine the correct calibration intervals. Equipment, which requires calibration, is used if satisfactory calibration has been achieved. If a specified calibration interval cannot be achieved or the calibration date has passed the equipment is not used. Equipment used infrequently, such that the manufacturer's recommendations cannot be followed, have their calibration verified prior to use.

Prior to being used in testing, new equipment (or any piece of equipment, which leaves the control of the Laboratory) undergoes the calibration procedures or performance verification.

All equipment and measuring instruments used to perform testing and measurement within the laboratory are calibrated as per schedule. For the purposes of interpretation, any item of test and measurement equipment, the uncertainty of which contributes less than 5% to the total uncertainty of measurement is considered insignificant.

Calibration records are maintained by the laboratory quality officer and are associated with the unique identifier of each equipment. These records include but are not limited to:

- Identity of the item of equipment.
- Serial number or unique identifier.
- Date of calibration
- Manufacturer's instructions or a reference to location and contact details
- Reference standard, certified reference material or reference material used for calibration
- Copies of all reports, results of calibration, and/or certificates of calibration
- Due date for the next calibration
- Identity of the individual performing calibration

When external calibrations are performed, service providers that demonstrate competence, measurement capability, and traceability are used. Calibration certificates from these providers contain the measurement results, including the

measurement uncertainty and/or a statement of compliance with an identified metrological specification.

Laboratory equipment requiring calibration is labelled or coded to indicate the calibration status, including the date when last calibrated and the due date for recalibration (or expiration criteria for when recalibration is due)

7.3 Reference Standards

Whenever possible, reference standards traceable to SI units (International system of units) are used. In situations where SI units cannot be used, certified reference material provided by a competent supplier are used if available.

The Laboratory acknowledges that it is not always possible or realistic to expect all measurements to be traceable to the International System of Units (SI), for example, traceability may be to a Certified Reference Material, or a specified method and/or consensus standard.

Where traceability is established using reference materials, traceability is accepted if the Reference Materials are included in the International Bureau of Weights and Measures (BIPM) Key Comparison Database (KCDB) or have been produced by a Reference Material Producer accredited.

Where Reference Materials are covered by the Joint Committee for Traceability in Laboratory Medicine, these are also considered as having established valid traceability.

Where reference materials do not meet the above criteria, they are treated as critical consumables, and Proteus Laboratory demonstrates that each Reference Material is suitable for its intended use.

Reference standards are only handled by competent personnel. A certificate of traceability, if applicable, is retained to ensure traceability.

7.4 Equipment Maintenance

Equipment is maintained as specified in the SOPs, daily maintenance logs and Manuals. A maintenance log and equipment manual are made available for each

equipment. In the absence of manufacturer's instructions, instructions are provided for in the technical procedures.

7.4.1 Preventive maintenance

Procedures (other than basic cleaning) for each equipment are developed by each section in the daily maintenance log and are performed according to a regular, predetermined schedule. All records of preventive maintenance are documented and maintained when required.

7.5 Maintenance Records

Maintenance records include:

- Type of equipment
- Equipment serial number or unique identifier
- Date of maintenance
- Adjustments or repairs made
- Identity of the individual performing maintenance

If maintenance is performed by a contracted engineer, e.g. servicing, the Quality Officer or designee retains the original maintenance records provided by the vendor.

7.6 Out of Service Equipment

Equipment that has been subjected to mishandling, gives erroneous results, or has been shown to be defective or outside-specified limits, is taken out of service. The equipment is clearly labelled "Out of Service" to prevent use until repaired and shown by calibration and verification to perform correctly.

Prior to returning a piece of equipment to use (out of service for any reason e.g. maintenance, malfunction, leaving the direct control of the Laboratory), correct operation demonstrated by recalibration or performance verification is done.

Laboratory personnel examines the effects, if any, of a malfunction on analysis results and implement a procedure for identification and control of nonconformities.

An exception may be made if the equipment failure is not directly related to its analytical function, such as a problem with peripheral equipment.

- Laboratory Equipment Management
- Identification and Control of NCs

- Internal quality control and External Quality Control
- ISO 15189:2012

9.0 Attachments/Annexes

- Appendix 1-Equipment Calibration Log
Reagents log sheet
- Annex 1: SOP attestation form

Appendix 1: Equipment Calibration / Service Log

	AU480	ACT5 AL	Aquios	Access	Centrifuges	GeneXpert	Pipettes timers' thermometers
Jan							
Feb							
March							
April							
May							
June							
July							
Aug							
Sept							
Oct							
Nov							
Dec							

Laboratory Information Management

This SOP describes how the Laboratory selects, validates, manages, maintain, backs-up and uses LIS to ensure patient confidentiality and restriction from access and tempering.

2.0 Scope

This procedure is applicable to all laboratory staff working at the Laboratory, the facility record personnel and visitors who intend to utilise or access Laboratory information and data.

3.0 Terms, Definitions and Abbreviations

3.1 Terms and Definitions

3.2 Abbreviations

ISO - International organization for standardization

SOP - Standard Operating Procedure

Skylims - Laboratory Information System

I.T - Information Technology

7.0 Procedure

7.1 Selection of LIS

The Laboratory use Skylims Management Information System; for accessing recording and capturing patient data.

Patient confidentiality is ensured by each staff member having a unique username and password. Confidentiality contract is also signed by all lab staff.

7.2 Authorities and Responsibilities

The Lab Manager takes full responsibility of ensuring that the Laboratory and other staff appropriately utilise the availed LIS.

Access to LIS is restricted using individual usernames and passwords for laboratory staff.

The access levels are given as per the rank of the staff member in the laboratory. The laboratory manager has access:

- Access patient data and information
- enter patient data and examination results
- change patient data or examination results
- authorize the release of examination results and reports.

7.3 Validation and Verification of LIS

The laboratory information system was validated by the supplier and verified before use in the laboratory. The Laboratory round off policy is 1.0 decimal place depending on the analyte. Monthly interface checks are done by selecting one report from each interfaced analyser.

The LIS operator manual is followed in operating the Lab Information system.

The LIS down times are logged as non-conformances to IT department for resolution.

When the LIS is down, copies of instrument print outs are issued to the clients.

Users of the laboratory are informed about downtimes (Instruments, stockout or LIS) and resumption of services.

7.4 Maintenance of the LIS

Maintenance is carried out by the IT department. Computerised data is backed up monthly on an external hard drive.

7.5 Receiving of samples

Samples received in the laboratory are evaluated against the request form, then captured into the laboratory information system.

Reporting and Reviewing of results

1.0 Purpose

To ensure that results are reported accurately, clearly, unambiguously and in accordance with specific instructions in the laboratory procedure.

2.0 Scope This SOP covers reporting of results, report attributes, report content, reviewing release of results and revised reports within Lab Information system. This SOP applies to all technical staff.

3.0 Terms, definitions and abbreviations 3.1 Terms and Definitions

Revised report: Test report that clearly identifies changes made to an original test report.

3.2 Abbreviations

- QO Quality Officer
- SOP Standard Operating Procedure
- CA Corrective Action
- QMS Quality Management System
- SANAS South African National Accreditation System.

7.0. Procedure

Results Entry on LIS

The Laboratory personnel enters manual results on the LIS. The result is double entered to ensure there are no transcription errors.

7.1 Review of Results/Report forms

- All laboratory results or report forms are completed by the laboratory technical staff as required by the specific test procedures (SOPs).
- The laboratory manager reviews the test results and test validity i.e. the request form is checked for data capturing errors and the final report is matched against the raw data from the instrument print out or manual test worksheet. Data capturing log sheet is maintained.
- the results/report forms are then authorised by the laboratory manager.

7.2 Release of results

The final report will have comments when the quality was compromised, critical and or urgent results phoned out.

All results provided verbally, are followed by a hard copy of the results.

Abnormal/ critical results are phoned out however, some clients prefer delivery of hard copy.

NB Automated selection and reporting of results is not performed in the lab

7.3 Revised / Amended reports

When an original report is revised, the revised report is clearly marked as a revised report an audit trail will be available on the LIS to show the person who made the changes, what was changed, date and time of the amendment.

7.4 Storage, Retention and disposal of clinical samples

Processed samples are stored at the appropriate temperatures depending on the sample stability and requirements

- Samples are stored chronologically by days of assay as in the table below
- After retention time, samples are discarded into biohazard bins with red plastic bags and slides and needles are discarded into sharps containers.
- Disposed samples are picked from the Laboratory by the contracted private waste management company.

Version review history table

Version No	Date of next review	Date reviewed	Reviewed by	Action taken/Remarks

