Proteus Laboratory Quality Manual			
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FOREWORD

This quality manual has been developed based on the ISO15189:2012, prevailing National regulations and applicable international accreditation requirements to define the laboratory policy framework required in establishment, implementation and maintenance of Quality Management System that guarantees quality in laboratory services provided by Proteus Laboratories.

The quality manual is reviewed annually to ensure its continued suitability to needs and requirements of the users. This document has been communicated to all the laboratory staff and subsequently all the laboratory staff are required to adhere to the established policies therein in order to sustain the quality management system.

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1.0 Scope

This quality manual describes the quality management system of Proteus Laboratories. The QMS is comprised of the quality policy along with the requirements of the ISO 15189:2012, SANAS (The accrediting body) and the Laboratory. There are documented procedures in place that provide step-by-step details on how processes are implemented and records that provide evidence of implementation. The Quality management system covers Pre-examination, Examination, Post examination and Management processes. The Quality Manual is implemented throughout all the sections of the Laboratory (Clinical Chemistry, Virology, Haematology and Management).

1.0 NORMATIVE REFERENCES

The following reference list of documents was used in developing Proteus Laboratory Quality manual

- ISO 15189:2012 Medical Laboratories-Requirements for quality and competency
- ISO 15190 - Medical Laboratories-Requirements for safety

2.1 TERMS, DEFINITIONS AND ABBREVIATIONS

2.1.1 Terms and Definitions

For the purposes of the Quality Manual, the following terms and definitions are applicable:

Accreditation: This is a process by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks
Audit: Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled

Corrective Action: Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

NOTE: Corrective action is taken to prevent re-occurrence whereas preventative action is taken to prevent occurrence

Document Control: It is a system to regulate the handling and management (including development of new documents, archiving, storing and destruction) of documents containing information that communicates policies, processes, procedures as well as records. Usually, it pertains documents that are part of the quality management system.

Document: Any information that provides direction (e.g., instructions including policy statements, textbooks, reference intervals and their origins, procedures, specifications, calibration tables, charts, posters, notices, memoranda, plans, software, drawings, regulations and standards).

Laboratory management: These are persons who manage the activities of Proteus Laboratories, and it comprises of the Laboratory Manager, Quality Officer/Manager, Safety Officer, laboratory technical staff, Customer care officer, Courier/driver and the Laboratory Director as the head.

Non-Conformity: Non-fulfilment of a requirement

Preventive actions: Action taken to eliminate the cause of a potential nonconformity or other undesirable potential situation.

NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent reoccurrence.

Procedure: Written work instructions that specify a way to carry out an examination or step in a process.

Process: Series of inter-related steps involved in an activity or examination that uses resources and is managed to transform inputs into outputs.

Quality Management System (QMS): Is defined as "coordinated activities to direct and control the Laboratory regarding quality.

Quality manual: A document specifying the quality management system of the Laboratory.

Quality objective: Something sought, or aimed for, related to quality.

NOTE: Quality objectives are generally based on the Laboratory *quality policy.*

Quality planning: Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives.

Quality policy: Overall intentions and direction of Proteus Laboratories related to the fulfilment of quality requirements as specified by laboratory management.

NOTE: The quality policy is consistent with the overall policy of the Proteus Laboratories *and provides a framework for the setting of quality objectives.*

Record: Any information that produces evidence (e.g., requisitions, examination results and reports, instrument printouts, laboratory workbooks and worksheets, accession records, calibration records, quality control records, records of audits, complaints and actions taken, external quality assessment records, instrument maintenance records, incident/accident reports, staff training and competency records, personnel records).

Referral laboratory: External laboratory to which a sample is submitted for an examination procedure due to unforeseen circumstances from the referring Laboratory.

Requirement: Need or expectation that is stated, generally implied or obligatory.

Review: Activity undertaken to ensure the suitability, adequacy, effectiveness, and efficiency of the subject matter to achieve established objectives.

Revision: Introduction of all necessary changes to the substance and presentation of a document to ensure its continuing suitability, adequacy, effectiveness to achieve established objectives.

User: Patient, Clinician, Staff using the services of the laboratory.

2.1.2 Abbreviations

For the purposes of the Quality Manual, the following abbreviations and acronyms found in the contents of the manual are applicable:

CA: Corrective Action

CAPR: Corrective Action and Problem report form

CLSI: Clinical Laboratory Standards Institute

HIV: Human Immune Deficiency Virus

ISO: International Organization for Standardization

LQMS: Laboratory Quality Management System

MRM: Management Review Meeting

PRL: Proteus Laboratories

NEQAS National External Quality Assurance Scheme

OPD: Outpatient Department

PA: Preventive Action

QA: Quality Assurance

QC: Quality Control

QMS: Quality Management System

QM: Quality Manager

SOP: Standard Operating Procedure

3.0 INTRODUCTION

3.1 Background of the Organisation

The medical laboratory Proteus Laboratories (hereinafter referred to as "the laboratory") aims to meet the requirements of ISO 15189: 2012 when carrying out work at its permanent facilities. Proteus Laboratories is a private entity and was established in 1996 by a group of qualified medical technologists determined to provide quality service to the disadvantaged. The laboratory is mainly a clinical pathology laboratory; however, it caters for the HIV management programmes and COVID 19 testing.

The organisation is made up of qualified technologists who are committed in delivering quality results to all patients, doctors and medical aid schemes. Ensuring professionalism and confidentiality always. It is currently servicing the Gauteng and Mpumalanga areas.

The laboratory operates according to the requirements of ISO15189:2012,

follows the Good Laboratory Practice (GLP) and Good Clinical Laboratory Practice (GCLP) guidelines.

Proteus Laboratories Practice number is **MT 7550626** and is displayed on all official letterheads.

Location and address

Physical Address

Bophelong Medical Centre

Proteus Laboratory

18069 Ngunguyane Street

Kwa-Thema

1575

Postal Address

P O. BOX 221

Kwa- Thema

1563

HOURS OF OPERATION

Monday to Friday from 8:00 - 20:00. Only urgent requests are covered on weekends, after normal working hours and public holidays.

3.3 Vision, Mission and core values

3.3.1 Vision

To be a Health Care Centre of Excellence.

3.3.2 Mission Statement

To provide holistic quality health services in a competent and friendly environment.

3.3.3 Core values

1. **Courtesy** in all dealings
2. **Accountability** in all actions
3. **Services** in all offerings
4. **Excellence** as a habit

3.4 Laboratory Services

Proteus Laboratories is a medical laboratory that provides a service in these areas: Haematology, Chemistry, Microbiology, Immunology, Serology, COVID 19 testing and HIV Monitoring. Specimens are collected and processed within a specified turnaround time. The laboratory has an effective, committed, friendly team that works to provide a quality service daily.

3.4.2.2 National and International Guidelines & Regulation

The Government of South Africa through the Department of Health and other regulatory authorities, from time to time develop guidelines and regulations pertaining to medical laboratory practices. Proteus Laboratories endeavours to implement these guidelines to enhance its ability to meet regulations. The guidelines/requirements include:

- HPCSA – Health professions council of South Africa

4.0 MANAGEMENT REQUIREMENTS

4.1 Organization and Management responsibility

4.1.1 Organization

4.1.1.1 General

Proteus Laboratories ensures that all the activities carried out continually comply with the requirements of ISO 15189:2012 standard while within the laboratory premises through adherence to policies and procedures set by the laboratory and those of the national accreditation body. All staff has access to the accreditation body website via the lab intranet.

4.1.1.2 Legal Entity

Proteus laboratory derives its authority to operate following registration with the Health Professional Council of South Africa with a certificate number MT 7550626. The copy of the registration certificate is displayed in the laboratory manager's office.

4.1.1.3 Ethical Conduct.

Proteus Laboratory Management is responsible for staff awareness of the ethical code of conduct. Laboratory personnel are taken through the ethical code of conduct during orientation. Which include:

a) Proteus Laboratories implemented the SOP on Ethical Code of Conduct in line with Health Professional Council of South Africa to ensure that there is no

involvement in activities that diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity.

b) Proteus Laboratory Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of work through ensuring that the requirements of SOP on Ethical Code of conduct are adhered to.

c) Where potential conflicts in competing interests may exist, they are openly and appropriately declared using the Conflict-of-interest report form **PRL-POL-001-F06**

d) Laboratory personnel are also aware of the requirement to ensure that all samples are dealt with in accordance with the Safety Manual **PRL-SAFETY-001**.

e) Proteus Laboratories respect all information it receives, and confidentiality is paramount. All staff or anyone that accesses laboratory information is required to read, understand and sign the confidentiality form before being given any information. This form is a binding document between the laboratory and the staff or any person accessing its information.

Ref:

● SOP on Ethical code of Conduct (**PRL-MGT-001)**

4.1.1.4 Laboratory Director

The Laboratory Director is the Chief Executive Officer responsible for the management of Proteus Laboratories including the delivery of Quality Health services to the people served and provision of resources and, has delegated the technical responsibilities to laboratory /Quality Manager to be responsible for laboratory's directorship.

Laboratory Director

The Laboratory Director is the head of the Laboratory and has the competence and responsibility for the laboratory services provided. The Competence of the laboratory Director is demonstrated through:

a. Participation in Continuing Professional Development (CPD).

b. Attendance at management review meetings to review laboratory issues and to set quality objectives.

The Laboratory Director's responsibilities include professional, scientific, consultative or advisory, organizational, administrative and educational matters.

The Laboratory Director maintains the ultimate responsibility for the overall operation and administration of the Laboratory and its compliance to the quality manual.

The duties and responsibilities include.

a) Providing effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.

b) Relating and functioning effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the health care community, and the patient population served, and providers of formal agreements, when required.

c) Ensuring that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users.

d) Ensuring the implementation of the quality policy.

e) Implementing a safe laboratory environment in compliance with good practice and applicable requirements.

f) Serves as a contributing member of the medical staff for those facilities served, if applicable and appropriate.

g) Ensuring the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results.

h) Selecting and monitoring laboratory supplies.

i) Selecting referral laboratories and monitoring the quality of their service.

j) Providing professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations.

k) Defining, implementing and monitoring standards of performance and quality improvement of the medical laboratory service(s).

l) Monitoring all work performed in the laboratory to determine that clinically relevant information is being generated.

m) Addressing any complaint, request or suggestion from staff and/or users of laboratory services.

n) Designing and implementing a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.

o) Planning and directing research and development, where appropriate.

p) The Laboratory director has delegated selected duties and responsibilities to the laboratory manager who is responsible for the day-to-day running of the laboratory. These are (d, e, h, i, k, m, n)

4.1.2 Management Responsibility

4.1.2.1 Management Commitment

The Laboratory Management is committed to the development and implementation of the quality management system and continually improves its effectiveness through:

a. Communicating to laboratory personnel the importance of meeting the needs and requirements of users through management review meetings and the established communication procedures documented in the Internal and External Communication SOP.

b. Establishing quality policy as seen in 4.1.2.3 in this manual.

c. Ensuring the quality objectives and planning are established as seen in 4.1.2.4 in this manual.

d. Defining responsibilities, authorities and inter-relationships of all personnel as seen in 4.1.2.5 in this manual.

e. Establishing communication processes that include meetings, memos, emails, verbal communications, suggestions and trainings as seen in 4.1.2.6 in this manual.

f. Appointing a Quality Manager with defined responsibilities as seen in 4.1.2.7

g. Conducting management reviews at least once a year as seen in 4.15 in this manual.

h. Ensuring that all personnel are competent to perform the assigned activities through staff training and competency assessment as documented in the procedure for Competency assessment and Personnel Training, respectively.

i. Ensuring the availability of adequate resources like personnel, reagents, equipment, and stationery to enable the proper conduct of Pre-examination, Examination and Post-examination as seen in 5.1, 5.2 and 5.3 in this manual.

Ref:

- ***Internal and External Communication***
- ***Competency Assessment***
- ***Personnel Training***

4.1.2.2 Needs of users

Proteus Laboratories ensures that the laboratory services, including appropriate advisory and interpretative services, meet the needs of laboratory users and this form part of the annual management review. This is also a commitment in the PRL Quality Policy (4.1.2.3). Which is achieved by:

a) Regular visits to the supporting doctors.

b) Seeking and assessing user feedback information about service satisfaction at least every twelve months and taking corrective and preventive actions to continuously improve performance and retain customer loyalty as documented in the procedure for resolution of customer complaints and feedback.

c) Using examination methods that are deemed fit for purpose through method verification and comparability of methods as seen in procedure for equipment/method verification or validation.

d) Ensuring quality of results through participation in inter-laboratory programs and performing internal quality controls as seen in 5.6 in this manual

e) Providing advisory services to clients as seen in 4.7 of this manual and Advisory Services SOP.

f) Establishment and reviewing of service agreements for providing laboratory services under defined conditions as seen in the procedure for service agreement.

g) A laboratory Clients Manual is provided to all supporting doctors.

Ref:

- *Resolution of customer complaints*
- *Advisory Services*
- *Service agreement*

4.1.2.3 Quality Policy

Laboratory Management has outlined the Quality Policy for the laboratory as stated below. The purpose of the quality policy is to provide guidance to staff and users, the course of action and measures that Proteus Laboratories implement in order to provide services of the highest quality. The Quality Policy is disseminated and explained to all staff. The policy is displayed at strategic locations such as laboratory notice boards, testing areas so that it serves as a guidance to the staff to maintain high quality services.

Proteus Laboratories is committed to providing quality, accurate, reliable and timely clinical laboratory testing that comply with the ISO 15189:2012 and other established international, national and professional regulations to all our users. The laboratory offers services in the disciplines of Clinical Chemistry, Haematology, Microbiology, Immunology and, Virology using verified methods fit for the intended use.

The laboratory is committed to and ensures good professional laboratory practice and conduct while offering services to its clients. The laboratory routinely collects user feedback through conducting customer satisfaction surveys that act as one of the bases for improvement of the quality management system.

The Quality policy is communicated and understood by all staff within the organization, provides a basis for the establishment of quality objectives and is reviewed annually at management review meeting for continuing suitability.

4.1.2.4 Quality objectives and planning

To implement the Quality policy, the laboratory established and monitors quality objectives. The objectives are set as per the "SMART" criteria i.e., Specific, Measurable, Achievable, Realistic and Time Bound.

The extent to which the set objectives are achieved is continually monitored and reviewed throughout the year. The decision on which objectives the laboratory tracks, is done during the management review meeting. The Management review meeting also determines whether the set objectives were successfully achieved or need to be revised.

The Quality Objectives are as stated below:

1. To ensure that < 3% of samples are rejected monthly.

2. To ensure that at least 80% of the accreditation test results (Clinical Chemistry, Haematology, Microbiology and Virology) are released within the stipulated TAT:

- urgent work 6 hours
- For routine work 24 hour
- HIV Monitoring tests 3 days
- Referral work 5 days

3. To ensure that all accreditation PT results meet a performance target of 80% per survey.

4. To ensure that 100% of the non-conformances are cleared within 30 working days.

5. To achieve at least 80% customer satisfaction per survey.

4.1.2.5 Responsibility, Authority and interrelationships.

The responsibility of each personnel is defined in the job description detailing the roles, responsibilities, key outputs, qualifications, competencies and reporting lines in the laboratory.

An organizational and laboratory organogram is available and details the internal reporting structures for laboratory personnel and the interrelationships among the personnel (Appendix 1 and 2).

The Authorities for the laboratory personnel are as indicated below Personnel	Responsible	Authority
Laboratory personnel	Laboratory personnel	Laboratory Manager
Quality Officer	Quality Officer	Laboratory Director
Safety Officer	Safety Officer	Laboratory Director
Laboratory Manager	Laboratory Manager	Laboratory Director
Laboratory Director	Laboratory Director	Laboratory Director

Table 1: Authority Matrix for Proteus Laboratories

All staff have been communicated regarding their roles and responsibilities and acceptance to those responsibilities is available in the personnel records. Due to human resource challenges, officers may handle more than one role. Deputies are appointed as need arises. Emails of appointing deputies are maintained by the quality / laboratory3 manager.

Ref:

- Resource Management

4.1.2.5.2 Appointment of deputies for key functions

Qualified and competent laboratory personnel are appointed as deputies to serve specific roles where necessary and to assist in the day-to-day running of the laboratory. Key positions are supported by deputies as detailed below:	
Position	**Deputy**
Laboratory Director	Laboratory Manager
Laboratory Manager	Laboratory Director
Quality Manager	Laboratory Director
Safety Officer	Lab Manager

Ref:

- Resource Management

4.1.2.6 Communication

Communication is vital for the effective performance as well as continual improvement of the QMS. Communication with the lab staff and clients occurs through emails, memos, training sessions, staff meetings, continuous medical education, phone calls and verbal conversations with personnel. The records of such communication are kept in the laboratory and are accessible to staff. Both Internal and External communication methods are implemented following the procedure for Internal and External communication.

4.1.2.6.1 Internal communication

Proteus Laboratories has established appropriate and effective communication processes for communication among staff. Communication is achieved through the following channels:

a) Meetings and Minutes

● Laboratory Meetings: The laboratory team meets quarterly.

b) Memos and letters

c) Continuous Medical Education (CME): are conducted by technical staff as need arises. The staff has access to the internet for accessing medical journals.

d) Emails

e) Communication log

4.1.2.6.2 External communication with stakeholders

The Laboratory Director is responsible for communication with the external stakeholders. The external stakeholders include:

a) Proteus Laboratories top management & supporting doctors.

c) The procurement unit.

d) External suppliers

Ref:

● *Internal and External Communication.*

4.1.2.7 Quality Manager

The Quality Manager is a Laboratory personnel responsible for establishing, implementing and maintaining the Quality Management System in Proteus Laboratories.

The quality manager is responsible for:

a) Ensuring that processes needed for the quality management system are established, implemented and maintained in conformance with applicable regulations, accreditation standards and customer requests/contracts.

b) Reporting to the laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement.

c) Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organisation.

d) Other duties as may be delegated

4.2 Quality Management System

4.2.1 General Requirements

Proteus Laboratories has established, documented, implemented, and maintains a quality management system that it continually improves for its effectiveness in accordance with the requirements of the ISO 15189:2012 as depicted below.

The quality management system provides for the integration of all processes required to fulfil Proteus quality policy, objectives that meet the needs and the requirements of the users.

Proteus Laboratories documented quality management system includes:

a) Statement of Quality Policy (4.1.2.3) and Quality Objectives and planning (4.1.2.4) of this Quality manual

b) Quality Manual as stated in clause 4.2.2.2

c) Procedures and records as required by the ISO 15189:2012 standard i.e., all documents indicated in the document control master list internal documents and external document logs

d) Documents and records that ensure the effective planning, operation, and control of its processes.

e) Copies of applicable regulations, standards and other normative documents that aid in its day-to-day processes.

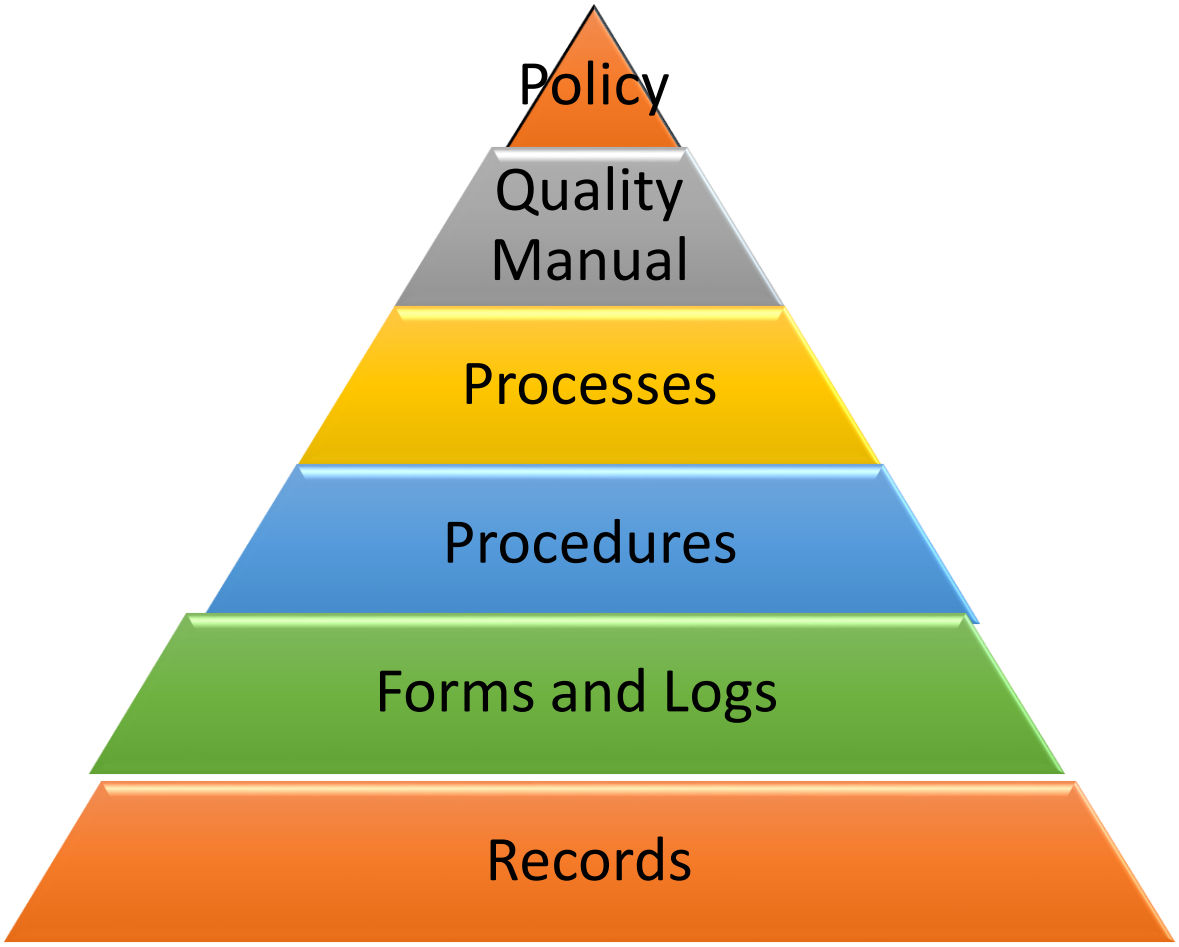


Figure 1: QMS structure of Proteus Laboratories

Level 1: Policy

The policy shows the overall intention and direction of the laboratory. Proteus Laboratories provides quality services to the users with an aim of customer satisfaction.

Level 2: Quality Manual

This Quality Manual describes the quality management system in accordance with the Quality Policy, objectives and the requirements of the ISO 15189:2012.

Level 3: Procedures

Describe the detailed systems and processes that systematically document from the start, the step-by-step process that is needed for tasks to be undertaken safely and with minimum harm to the environment.

i. Procedures describe the practical ways in which intentions in the quality policy are translated into action.

ii. They describe how the implementation of the processes in the quality management system is done.

iii. The laboratory has the core and supporting processes in the quality management system as described:

● The core processes of the quality management system are pre-examination, examination and post-examination processes, which translate the inputs (customer feedback, audit results, process performance, and continual improvement, amongst others) to the outputs as quality results and services.

● There are also supporting processes for continual improvement, monitoring and evaluation processes, which include internal audits, management reviews, corrective actions, and preventive actions as detailed in this manual. refer to figure 2

Level 3: Work instructions

Work instructions describe specific steps in the SOPs to accomplish tasks.

Level 3: Forms and logs-These provide current and historical evidence of processes.

The Laboratory has:

a) Determined the processes needed for the quality management system and ensures their applications throughout the laboratory as depicted in figure 1 above.

b) Determined the sequence and interaction of these processes:

c) Determined criteria and methods needed to ensure that both the operation and control of these processes are effective. The Laboratory Quality Management System is as depicted below:

d) Ensuring the availability of resources: For the above processes to run, the needed resources include personnel (trained and competent), accommodation and environmental conditions, laboratory equipment, reagents and consumables, external services and supplies and laboratory information Management system through planning based on the test statistics available and needs of the users.

e) Monitors and evaluates these processes.

f) Implements actions necessary to achieve planned results and continual improvement of these processes

4.2.2 Documentation Requirements

4.2.2.1 General Requirements

Proteus Laboratories has established, documented and maintains a four-tier document structure. The effectiveness of the document system is continually improved as documented in the SOP on continual improvement.

The laboratory documented management system includes:

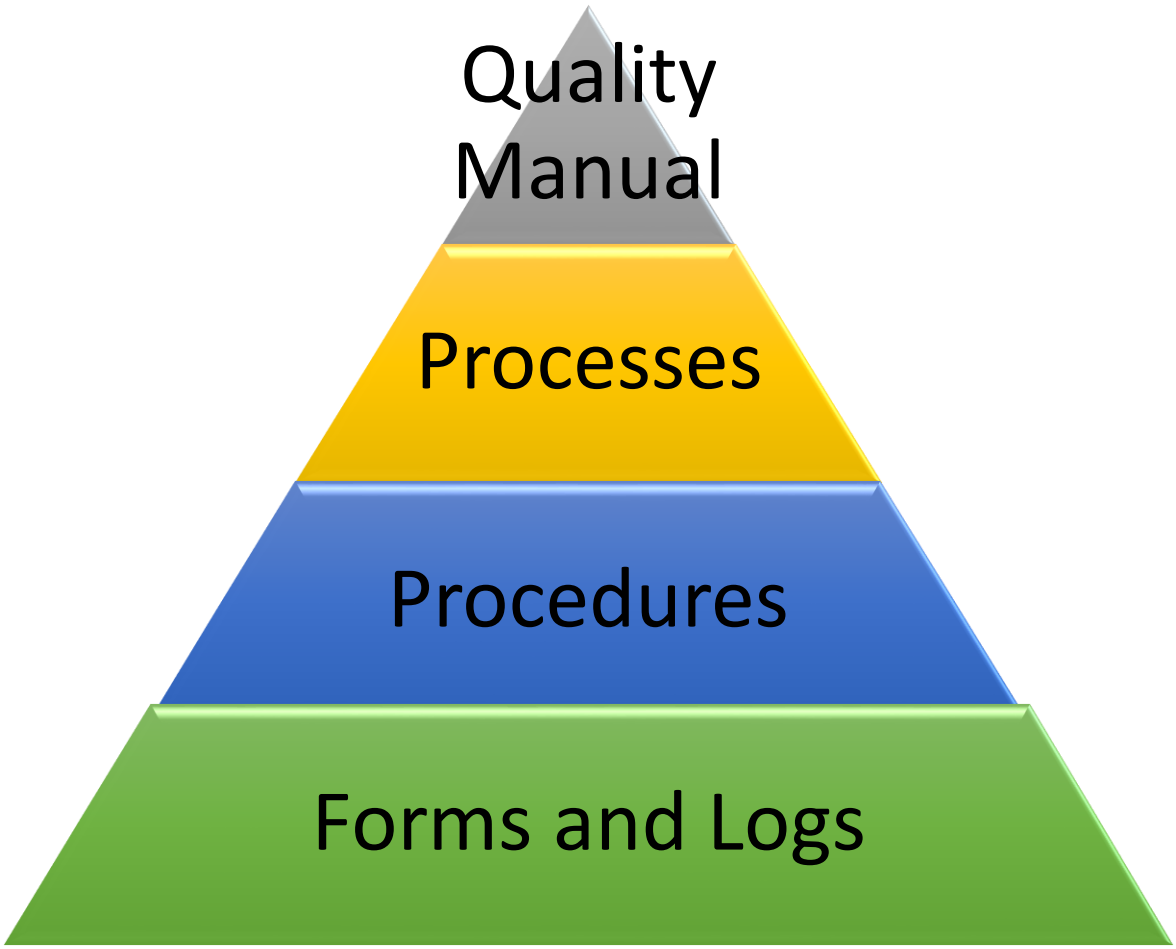
a) Statement of Quality Policy (4.1.2.3) and Quality Objectives and planning (4.1.2.4) of this Quality manual

b) Quality Manual as stated in clause 4.2.2.2

c) Procedures and records as required by the ISO 15189:2012 standard i.e., all documents indicated in the document control master list internal documents and external document logs.

d) Documents and records that ensure the effective planning, operation, and control of its processes.

e) Copies of applicable regulations, standards and other normative



documents that aid in its day-to-day processes. External documents indicated in the document control log.

Figure 2: Document Structure at Proteus Laboratories

The documentation takes a four-tier hierarchical structure, comprising:

Level 1

Quality Manual which states what is done at Proteus Laboratories and the policy i.e., overall intentions and direction of a laboratory.

Level 2

Processes which describe how, it happens at the laboratory.

Level 3

Procedures and Job Aids, these describe stepwise instructions on how to accomplish tasks.

Level 4

Forms, logs, labels and tags, this is evidence or work done.

Note: External documents encompass all levels of the documentation structure and are referred to as reference documents.

Ref

- *Continual Improvement*
- *Document and Record control*

4.2.2.2 Quality manual

Proteus Laboratories has established and maintains a quality manual that includes,

a. the quality policy (4.1.2.3) and the Quality Objectives and planning (4.1.2.4).

b. a description of the scope of the quality management system (4.2.2.1).

c. a presentation of the organization and management structure of the Laboratory (Appendix 2).

d. a description of laboratory management roles and responsibilities (4.1.2.5.1).

e. a description of the structure and relationship of the documentation used in the quality management system (4.2.2.1).

f. The documented policies established for the quality management system of Proteus Laboratories and referenced documents as documented in the document control for internal documents and external document.

All Proteus Laboratories staff are trained; have access to the quality manual, acknowledged understanding and pledge to implement the quality manual and its referenced documents.

4.3 Document Control

Proteus laboratory has established and implemented a Document Control SOP to control all internal and external documents. The document control procedure ensures that obsolete documents are removed from circulation to prevent unintended use. The documented procedure ensures that the following are met:

a) Review of all documents by authors, issued as part of the quality management system are reviewed and approved by the quality Manager or designee and authorized by the Lab manager and Lab Director.
b) All documents at Proteus Laboratories are identified to include, Laboratory name and location, the document Title, document number, unique identifier on each page, page number to total number of pages at the bottom, current Version number, authority for issue and effective date.

c) Distribution of current authorized versions at points of use which are tracked using a master list for Internal and External documents
d) Current authorized versions and their distribution are identified by a means of the document control logs for internal and external documents. Only current, authorized versions of applicable documents are available at the point of use.
e) Amendments on quality management system documents is performed by the author, quality officer, lab manager or designee. This can be written by hand and clearly marked by a single line through and dated.
f) Changes to documents are identified on version change history log.
g) All Documents remain legible.
h) All documents are reviewed annually. However, revisions are made in case of major changes (e.g., Change in procedural steps, Calibrations, change in authorizing authority) before the designated review period.
i) All obsolete documents are marked as OBSOLETE, with the discontinuation date to prevent unintended use and a copy is archived as defined in the Document and Record control SOP.
j) Obsolete documents are promptly removed from all points of issue and at least one copy is retained for specific period in accordance with SANAS TG22 document retention period.

Ref:

- *Document and Record control SOP* ***(PRL MGT 003)***

4.4 Service agreements

4.4.1 Establishment of Service Agreements

Proteus Laboratories has a documented procedure for establishment and review of agreements for providing medical laboratory services. Each request accepted by Proteus Laboratory for examination is considered an agreement.

Agreements to provide medical laboratory services at Proteus Laboratories considers the request, examinations and the report. This agreement specifies the information needed on the request to ensure appropriate examination and results interpretation for intended use.

The laboratory meets its service agreements through the following:

a) Providing Proteus Laboratory customers and users with Laboratory clients handbook that details the processes to be used at each department including the examination processes to be used.

b) Providing resources and capacity required to meet the needs of the users, SOP for resource management ensures personnel are commensurate with workload.

c) Performing trainings and competence assessments for laboratory personnel as documented in the SOP for Competency Assessment to ensure that they have the skills and expertise necessary for performance of the lab examinations.

d) Performing examinations using verified methods and equipment that meet the needs of users. This is documented in the validation, verification of examination procedures and equipment SOP.

e) Informing the users on deviations from the agreement that impact on the examination results. This is done by the laboratory manager and records of

these communications are retained as documented in the SOP for Communication.

f) Reference is made to all work done by referral laboratory on behalf of Proteus Laboratories in the events that work within the scope of service is referred.

4.4.2 Review of service agreements

Reviews of agreements to provide medical laboratory services include all aspects of the agreement. Records of the reviews include any changes to the agreement and any pertinent discussions. When an agreement needs to be amended after laboratory services have commenced, the requester is notified of any deviations/amendments and this communication is documented in the communication log. The final report will show what was amended. The same agreement review process is repeated, and amendments communicated to all the affected parties.

Ref:

- *Service agreement* ***(PRL MGT 004)***
- *Resource Management*
- *Validation, verification of Examination Procedures and equipment*
- *Internal and External Communication*

4.5 Examination by Referral Laboratories.

4.5.1 Selection and evaluation of Referral Laboratories and Consultants

Proteus Laboratories has a documented procedure for selecting and evaluating referral laboratories and consultants that provide examinations and interpretation that are beyond its scope or when it cannot perform the examinations. The procedure ensures the following conditions are met:

a) Proteus Laboratory in consultation with the users where appropriate selects referral laboratories and consultants, monitors the quality of

performance to ensure competence in performing the requested tests and those that do not meet this criterion are dropped from the list of referral Laboratories.

b) The agreements made are annually reviewed and evaluated to meet the requirements of ISO 15189:2012, records of reviews, registers are maintained by the Quality Manager

c) All requests and results of samples referred are available in the laboratory registers or LIS.

d) Proteus Laboratories maintains a register of reference laboratories and consultants it uses.

e) When samples are referred for testing, they are documented in LIS and when the results are returned, they are verified against the entries made in the LIS. Requests and results of all referred samples are kept in the LIS.

4.5.2 Provision of Examination Results.

Proteus Laboratories provides examination results to the requester and all referral work is recorded in the LIS.

The Laboratory does not prepare the report but ensures that all essential elements of the results reported are not altered that helps in clinical interpretation. The report is issued without any alteration or amendments or additional remarks.

The lab has adopted most appropriate means for reporting reference results considering turnaround times, measurement accuracy, transcription process and interpretative skill requirements. In case additional interpretative details are needed by the clinicians, collaboration is in place with the referral laboratory, and this is not hindered by commercial or financial constrains as Memoranda of Understanding are in place to offer the service.

Ref:

- *Examination by referral labs and consultants (PRL MGT 005)*

4.6 External services and supplies

Proteus Laboratories has a documented external services and Supplies management procedure for evaluation of supplies received from the suppliers and a list of selected and approved suppliers is maintained at the laboratory for reference.

Proteus Laboratories uses a standard supply order form (available on Skylims) showing product specifications to place orders for the required items or products from suppliers. The laboratory evaluates the performance of the suppliers against the order placed using the procedure for external services and supplies to ensure that purchased services or items consistently meet the stated criteria and give user feedback.

Ref:

- ***External Services and Supplies (PRL MGT 006)***

4.7 Advisory Services

In order to keep the laboratory users informed about our services, Proteus Laboratories uses a client handbook, memos, verbal information, meetings to communicate to the users about the services offered and get feedback for improvement as documented in the Advisory services SOP.

The competent technical personnel communicate to the client the following:

a) Scope of services offered, specimen type and examination choice, Turn Around Time, clinical indications and limitations of examination procedures and the frequency of requesting for the tests. This is also documented in the client's manual.

b) Giving information on individual clinical cases as need arises.

c) Interpretation of results by competent personnel.

d) Ensuring cost effective utilisation of Laboratory services.

e) Scientific information and the available supplies in case of failure to meet the set criteria.

Ref:

- *Advisory services **(PRL MGT 007)***

4.8 Resolution of complaints

All complaints are recorded on a complaint log form, investigated and action taken, and the information is treated as confidential.

The customer complaint process including outputs are reviewed and presented to laboratory staff during lab meetings.

Ref:

- *Resolution of customer complaints and feedback **(PRL MGT 008)***

4.9 Identification and control of Nonconformities

Proteus Laboratories uses procedure for Identification and control of non-conformances to identify and control Non-Conforming work in the quality management system including, pre-examination, examination, post examination and management phases.

The Laboratory Identifies nonconforming work through clients' complaints, internal quality control data, instrument calibration reports, verification of supplies, Inter-laboratory comparisons, personnel reports, internal and external audits, management reviews and report and certificate checking.

All nonconforming work is recorded and documented in the corrective action form and the quality manager or designee reviews the identified NCs on quarterly basis to detect trends and initiate a corrective action.

Laboratory management is responsible for ensuring nonconforming work/processes are handled according to the procedure and are documented in the corrective action form.

The medical significance of nonconforming examination is considered where appropriate, the requesting clinician or authorized individual responsible for using results is informed. The results of any nonconforming or potentially nonconforming examination already released are recalled or appropriately identified. Records of non-conformities are documented, recorded and are reviewed quarterly to detect trends and initiate corrective action.

Ref:

- *Identification and Control of NC* ***(PRL MGT 009)***
- *Corrective Action and Preventive Action* ***(PRL MGT 009)***

4.10 Corrective action

The laboratory is committed to ensuring that where errors have been identified, their resolution goes beyond addressing the symptoms of the problems to establishing the root cause of the problem and removing them in order to ensure that the problem does not reoccur. The laboratory has a procedure for Corrective Action and Preventive Action that guides the process of implementing corrective action when one of the following is identified:

- Non-conforming work,
- Deviations from the policies and procedures in the management system,
- Deviations from required technical operations.

The procedure for corrective actions and preventive actions includes investigating; determining the root cause of the non-conformance; evaluating the need for Corrective action to prevent the re-occurrence of non-conformities; determining and implementing the corrective action

needed; recording the results of Corrective action and reviewing the effectiveness of corrective action taken.

Corrective actions are documented in the corrective action form, and any changes resulted from the corrective action investigation are implemented.

Ref:

● *Corrective Action and Preventive Action* ***(PRL MGT 009)***

4.11 Preventive action

In addition to the corrective action discussed in 4.10, the Laboratory is further committed to proactively identifying potential errors and removing their probable root causes to ensure such errors do not occur.

Sources for needed improvements and potential sources of non-conformance are identified according to the process described in the laboratory's procedure for Corrective action and Preventive Actions and are part of the management review process. Preventive actions plans are developed, implemented, and monitored to address the identified opportunities for improvement.

Procedure for Corrective action and Preventive Actions explains the reviewing of laboratory data and information to determine where potential nonconformities exist; determining root causes of potential nonconformities; evaluating the need for preventive; determining and implementing preventive action needed; recording the results of preventive action taken; and reviewing the effectiveness of the preventive action taken.

Ref:

● Corrective Action and Preventive Action **(PRL MGT 009)**

4.12 Continual Improvement

The laboratory has implemented a Continual Improvement procedure and procedure for Management Review in its quality management system including pre-examination, examination and post examination processes to compare the laboratory's actual performance to its intentions as stated in the quality policy and objectives.

Improvement activities target areas of highest priority based on risk assessment. Various action plans ensure the planning and execution of both corrective and preventive actions to continually improve the system and its effectiveness. Other means that contribute to the continual improvement of PRL quality management system include:

i. Review of the documentation annually to keep abreast of technological changes,

ii. Systematic monitoring of quality indicators including Customer satisfaction, Turn Around Times, EQA results, Sample rejection

iii. Assessment of user satisfaction

iv. Quarterly laboratory / users meeting to discuss service needs.

v. Internal audits

vi. External quality assessment.

vii. Management of Non-Conformities

viii. Management Review

The results of these evaluation and improvement processes are available to staff and users as required. Analysis, recording, and interpretation of the data form part of the management review meetings.

Ref:

- *Continual Improvement SOP* ***(PRL MGT 012)***

4.13 Control of Records

The SOP on Document and Records control is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose quality and technical records. Quality records include but not limited to reports from internal audits and management reviews as well as corrective and preventive action records. The Laboratory Manager or designee is the custodian of all laboratory records.

All records, including test reports, are safely stored and held secure in access-controlled areas when necessary and in confidence to the customer when required.

Records for archival are maintained in designated archival areas with suitable environment to prevent damage, deterioration, and loss and are readily retrievable.

Corrections to hard copy records are made using a single line strike through with indelible ink, writing the correct information alongside, and initialling and dating each correction.

The retention times for records is defined in the Documents and Records SOP. Records may be in the form of any type of media, such as hard copy.

These records may include but not limited to the following.

a) Supplier selection and performance, and changes to the approved supplier list;

b) Staff qualifications, training and competency records;

c) Request for examination;

d) Records of receipt of samples in the laboratory

e) Information on reagents and materials used for examinations (e.g., lot documentation, certificates of supplies, package inserts);

f) Laboratory workbooks or work sheets;

g) Instrument printouts and retained data and information.

h) Examination results and reports.

i) Instrument maintenance records, including internal and external calibration records.

j) Calibration functions and conversion factor.

k) Quality control records.

l) Incident records action taken.

m) Risk management records.

n) Nonconformities identified and immediate or corrective action taken.

o) Preventive action taken.

p) Complaints and actions taken.

q) Records of internal and external audits.

r) Inter laboratory comparisons of examination results.

s) Records of quality improvement activities.

t) Minutes of meetings that record decisions made about the laboratory's quality management activities.

u) Records of management reviews.

All these quality and technical records are available for laboratory management review.

Ref:

- *Document and Record Control SOP* ***(PRL- MGT 003)***

4.14 Evaluation and Audits

4.14.1 General

Proteus Laboratories plans and implements the evaluation and audit processes in accordance with the SOP on Internal Audits needed to:

a) Demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users.

b) Ensure conformity to the quality management system.

c) Continually improve the effectiveness of the quality management system

All the results of evaluation and improvement activities are included in the input to the management review.

4.14.2 Periodic review of requests, and suitability of procedures and sample requirements

The laboratory management annually reviews the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.

Management review also cover reviews of sample volume, collection device and preservative requirements for blood, other body fluids, tissue and other sample types as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected, and the sample is properly collected to preserve the measurand.

Ref:

- *Management Review (PRL MGT 015)*
- *Client's manual*

4.14.3 Assessment of user feedback

Management implemented the procedure on Resolution of Customer Complaints and feedback when it seeks information relating to user perception as to whether the service meets the needs and requirements of the users. The method of obtaining and using this information includes cooperation with users or their representatives in monitoring the laboratory's performance, while ensuring that confidentiality is adhered to. The records of customer feedback are available in the laboratory.

Ref:

- *Resolution of customer complaints and feedback* ***(PRL MGT 008)***

4.14.4 Staff suggestions

Management encourages staff to make suggestions through staff meetings or any other media for improvement of any aspects of the laboratory service. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of the suggestions and action taken by the management are maintained by the laboratory manager and are captured in the staff suggestion book.

Ref:

- *Internal and External Communication*.

4.14.5 Internal Audit

The laboratory conducts internal audits at least annually of all its processes to verify that its operations continue to comply with the requirements of this quality management system and ISO 15189:2012. Where gaps that cast doubt on the effective performance of the laboratory management system

(established through customer complaints, quality control, management reviews or others), institutes corrective action.

It is the responsibility of the Quality Manager to plan and organize audits as described by the laboratory audit program and requested by management.

Procedure for Internal Audit describes the planning and carrying out of the internal audits. Audits are scheduled based on the status and importance of activity to be audited. If criticality of the work being performed deems necessary, audit intervals are adjusted. The Quality Officer and/or laboratory Manager have authority to adjust audit intervals.

Trained and competent personnel are responsible for conducting internal audits. Audits are performed by personnel other than those who perform the work being audited where resources permit.

Audit results are recorded and shared with the personnel responsible for the area being audited. The audit team initiates corrective actions on audit findings, as necessary. The person identified as responsible resolves corrective actions according to the procedure for identification and control of Non-conformities. The corrective action activity verifies the actions taken and ensures the effectiveness of the corrective action.

Ref:

- *Internal audits* ***(PRL MGT 014)***

4.14.6 Risk management

The Laboratory evaluates the impact of work processes and potential failures on examination results as they affect patient safety and modifies processes to produce or eliminate the identified risks and document decisions and actions taken. Risk management is extensively covered in the SOP for risk Management.

Ref:

- *Risk Management*

4.14.7 Quality indicators

Proteus Laboratories has established quality indicators which monitors and evaluates performance throughout critical aspects of pre-examination, examination, post-examination and management processes. Systematic monitoring of quality indicators including Customer satisfaction, Turn Around Times, EQA performance, Sample rejection, Stock out.

The Laboratory in consultation with its users have established turnaround times for each of its examination that reflect clinical needs. The laboratory daily evaluates whether it's meeting the established turnaround times

Ref:

- *Continual Improvement* ***SOP (PRL MGT 012)***
- *Clinician's Handbook*

4.14.8 Review by external organization.

When reviews by external organization indicate the laboratory have nonconformities or potential nonconformities, the Laboratory takes appropriate immediate actions and as appropriate, corrective action or preventive action to ensure continuing compliance with requirements of the ISO 15189:2012 standard. Records are maintained of the reviews and corrective actions and preventive actions taken.

Ref:

- *Identification and Control of NC* ***(PRL MGT 009)***
- *Corrective Action and Preventive Action* ***(PRL MGT 009)***

4.15 Management Review

4.15.1 General

The management of the laboratory reviews the quality management system including pre-examination, examination, and post-examination and testing activities at least biannually to ensure the effectiveness, adequacy, suitability and continued support to patients care, and introduce necessary changes or improvements. Action items are assigned to personnel and are executed within agreed times. Documentation of the review is provided to other laboratory staff. The procedure for Management Review explains how management reviews are conducted.

4.15.2 Management Review Input

The input to the Management review meetings includes information from the result of evaluation of at least the following agenda items.

a) The review of requests, and suitability of procedures and sample requirements.

b) Assessment of user feedback.

c) Staff suggestions.

d) Internal audits.

e) Risk management.

f) Use of quality indicators.

g) Review by external organizations.

h) Results of participation in inter laboratory comparison programs.

i) Monitoring and resolution of complaints.

j) Performance of suppliers.

k) Identification and control of non-conformities.

l) Result of continual improvement, including current status of corrective actions and preventive actions.

m) Follow up actions from previous management reviews.

n) Changes in volume and scope of work, personnel, and premises that could affect quality management system.

o) Recommendations for improvement, including technical requirements.

The annual management review meeting is chaired by the Quality Manager and is attended by but not limited to the following:

a. Laboratory Director

b. Laboratory manager

c. Laboratory Quality Manager

e. Laboratory safety Officer

f. Lab supervisors

4.15.3 Review Activities

The review analyses the input information for cause of non-conformities, trends and patterns that indicate process problems.

The review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

The quality and appropriateness of the laboratory's contribution to the patient care is objectively evaluated.

4.15.4 Review Output

Minutes of the management review meeting are recorded and are shared with laboratory staff.

The output from the management review is incorporated into a record that documents decisions and actions made during the management review which are related to:

a) Improvement of effectiveness of the quality management system and its processes

b) Improvement of service to the users

c) Resource needs.

Management ensures that actions arising from management review are completed within the agreed upon time.

Ref:

- *Management Review (**PRL MGT 015**)*
- *Continual Improvement SOP **(PRL MGT 012)***

5.0 TECHNICAL REQUIREMENTS

5.1 PERSONNEL

The laboratory has a documented procedure for personnel management and maintains records for all personnel to indicate compliance with requirements.

SOP for Resource management manual PRL-RMM-001

5.1.2 PERSONNEL QUALIFICATIONS

Laboratory management has documented personnel qualifications for each position. The qualifications reflect the appropriate education, training, experience and demonstrated skills needed for the tasks performed. The personnel making judgments with reference to examinations have the applicable theoretical, practical background and experience.

5.1.3 Job descriptions

The laboratory has job descriptions that describe responsibilities, authorities and tasks for all personnel.

The job descriptions and personnel qualifications for laboratory technical personnel are derived from the Public Service scheme of service.

5.1.4 PERSONNEL INTRODUCTION TO THE ORGANIZATIONAL ENVIRONMENT

The laboratory has a program to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services.

An orientation form is filled for each staff. Orientation is completed within a month of joining the organisation.

5.1.5 TRAINING

The laboratory provides training for all personnel which include the following areas:

a) The quality management system.

b) Assigned work processes and procedures.

c) The applicable laboratory information system.

d) Health and safety, including the prevention or containment of the effects of adverse incidents.

e) Ethics.

f) Confidentiality of patient information.

Personnel that are undergoing training are always supervised by the laboratory manager. The effectiveness of the training program is reviewed yearly. The above trainings are planned and at least one of them is done within 12 months of a calendar year.

However other trainings also occur as need arises for example on technical procedures. The laboratory staff also attend planned external trainings by suppliers.

5.1.6 COMPETENCE ASSESSMENT

Following appropriate training, the laboratory assesses the competence of each person to perform assigned managerial or technical tasks according to established criteria. Reassessment takes place annually. Retraining occurs as need arises.

Competence of laboratory staff is assessed by using any combination or all the following approaches under the same conditions as the general working environment:

a) Direct observation of routine work processes and procedures, including all applicable safety practices.

b) Direct observation of equipment maintenance and function checks.

c) Monitoring the recording and reporting of examination results.

d) Review of work records.

e) Assessment of problem-solving skills.

f) Examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples.

The quality officer is responsible for assessing staff on technical activities while the lab director assesses the staff for managerial tasks. The laboratory director may delegate the responsibility to the lab manager to assess staff for some managerial tasks.

Reassessment of staff competence is ongoing through reviewing of personnel assigned tasks, e.g., maintenance records, IQC or EQA.

Assessment tools are developed by any assigned personnel, reviewed by quality officer and approved by lab manager.

The assessment tools developed are test or task specific.

A staff is deemed competent if they score 100% for technical tasks and 80% for managerial tasks.

Assessment for newly recruited staff occurs at not more than one month from the time of appointment.

5.1.7 REVIEWS OF STAFF PERFORMANCE

In addition to the assessment of technical competence, the laboratory ensures that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.

Staff performance is reviewed continually through the results they have generated, e.g., equipment maintenance, IQC and EQA reviews.

Staff performance is reviewed quarterly by performance appraisals.

5.1.8 CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT

A continuing education program is available to personnel who are in managerial and technical processes. The effectiveness of the continuing education program is reviewed annually. Staff has access to online programmes for continuing professional development.

5.1.9 PERSONNEL RECORDS

Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel are maintained. These records are readily available to relevant personnel and include but not be limited to:

a) Educational and professional qualifications.

b) Copy of certification or license, when applicable.

c) Previous work experience.

d) Job descriptions.

e) Introduction of new staff to the laboratory environment.

f) Training in current job tasks.

g) Competency assessments.

h) Records of continuing education and achievements.

i) reviews of staff performance.

j) Reports of accidents and exposure to occupational hazards.

k) Immunization status, when relevant to assigned duties.

PROTEUS LABORATORIES has established a procedure for personnel management and maintenance of records for all personnel to cover all the requirements of the ISO 15189; 2012 standard.

Refer to SOP on Resource Management Manual PRL-RMM-001

5.2 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

The laboratory has space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory evaluates and determines the sufficiency and adequacy of the space allocated for the performance of the work.

5.2.2. LABORATORY AND OFFICE FACILITIES

The laboratory and associated office facilities provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met:

a) Access to areas affecting the quality of examinations is controlled.

b) Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.

c) Facilities for examination allow for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.

d) Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.

e) Safety facilities and devices are provided, and their functioning are annually verified.

5.2.4 STORAGE FACILITIES

Storage space and conditions are provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results. Clinical samples and materials used in examination processes are stored in a manner to prevent cross contamination. Storage and disposal facilities for hazardous materials are appropriate to the hazards of the materials, as specified by applicable requirements.

5.2.4 STAFF FACILITIES

There is adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.

5.2.5 PATIENT SAMPLE COLLECTION FACILITIES

Patient samples are collected by the clinicians offsite the laboratory.

5.2.6 FACILITY MAINTENANCE AND ENVIRONMENTAL CONDITIONS

Laboratory premises are maintained in a functional and reliable condition. Work areas are cleaned and well maintained. The laboratory monitors, controls and records environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff.

Attention is paid to factors such as light, dust, noxious or hazardous fumes, humidity, electrical supply, temperature and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.

Refer to Laboratory safety manual PRL-Safety-001

5.3 LABORATORY EQUIPMENTS, REAGENTS AND CONSUMABLES

For the purposes of this quality manual, laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems.

Reagents include reference materials, calibrators and quality control materials etc.; consumables include Test kits, pipette tips, glass slides, sample containers etc.

5.3.1 EQUIPMENT

The laboratory has a documented procedure for the selection, purchasing and management of equipment. The laboratory is furnished with equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage). The laboratory replaces equipment as needed to ensure the quality of examination results.

5.3.1.2 EQUIPMENT ACCEPTANCE TESTING

The laboratory verifies upon installation and before use that the equipment can achieve the necessary performance and that it complies with requirements relevant to any examinations concerned.

Each item of equipment is uniquely labelled/marked with a serial number.

5.3.1.3 EQUIPMENT INSTRUCTIONS FOR USE

Equipment is always operated by trained and authorized personnel. Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment are readily available. The laboratory has procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

Refer to SOP Resource Management Manual PRL-RMM-001

5.3.1.4 EQUIPMENT CALIBRATION AND METROLOGICAL TRACEABILITY

The laboratory has a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:

a) Considering conditions of use and the manufacturer's instructions.

b) Recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment.

c) Verifying the required measurement accuracy and the functioning of the measuring system at defined intervals.

d) Recording the calibration status and date of recalibration.

e) Ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated.

f) Safeguards to prevent adjustments or tampering that might invalidate examination results.

Metrological traceability is to a reference material or reference procedure of the higher metrological order available.

NOTE: Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer.

Such documentation is acceptable if the manufacturer's examination system and calibration procedures are used without modification. Where this is not possible or relevant, other means for providing confidence in the results are applied, including but not limited to the following:

— use of certified reference materials.

— Examination or calibration by another procedure.

— Mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

5.3.1.5 Equipment maintenance and repair

The laboratory has a documented program of preventive maintenance which, at a minimum, follows the manufacturer's instructions.

Equipment is maintained in a safe working condition and in working order. This includes examination of electrical safety; emergency stop devices where they exist and the safe handling and disposal of chemical and biological materials by authorized persons.

At a minimum, manufacturer's schedules or instructions or both is used. Whenever equipment is found to be defective, it is taken out of service and clearly labelled. The laboratory ensures that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria.

The laboratory examines the effect of any defects on previous examinations and institute immediate action or corrective action. The laboratory takes reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.

When equipment is removed from the direct control of the laboratory, the laboratory ensures that its performance is verified by running controls before being returned to laboratory use.

Refer to SOP Resource Management PRL-RMM-001

5.3.1.6 EQUIPMENT ADVERSE INCIDENT REPORTING

Adverse incidents and accidents that can be attributed directly to specific equipment are investigated and reported to the manufacturer and appropriate authorities, as required for example in-country service providers.

Refer to SOP Resource Management Manual PRL-RMM-001

5.3.1.7 EQUIPMENT RECORDS

Records are maintained for each item of equipment that contributes to the performance of examinations. These equipment records include, but not be limited to, the following:

a) Identity of the equipment.

b) Manufacturer's name, model and serial number or other unique identification.

c) Contact information for the supplier or the manufacturer.

d) Date of receiving and date of entering service.

e) Location.

f) Condition when received (e.g., new, used or reconditioned); g) manufacturer's instructions.

h) Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory.

i) Maintenance carried out and the schedule for preventive maintenance.

j) Equipment performance records that confirm the equipment's ongoing acceptability for use.

k) Damage to, or malfunction, modification, or repair of the equipment.

The performance records referred to in (j) include copies of reports/certificates of all calibrations and/or verifications including dates,

times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all this requirement. These records are maintained and are readily available for the lifespan of the equipment or longer.

5.3.2 REAGENTS AND CONSUMABLES

The laboratory has a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.

5.3.2.2. REAGENTS AND CONSUMABLES — RECEPTION AND STORAGE

The laboratory receives and store received reagents and consumables according to manufacturer's specifications.

5.3.2.3. REAGENTS AND CONSUMABLES — ACCEPTANCE TESTING

Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, is verified for performance before use in examinations by running quality controls. Consumables that can affect the quality of examinations are verified for performance before use in examinations.

5.3.2.4 REAGENTS AND CONSUMABLES — INVENTORY MANAGEMENT

The laboratory has established an inventory control system for reagents and consumables. The system for inventory control segregates uninspected and unacceptable reagents and consumables from those that have been accepted for use.

5.3.2.5 REAGENTS AND CONSUMABLES — INSTRUCTIONS FOR USE

Instructions for the use of reagents and consumables, including those provided by the manufacturers, are readily available.

5.3.2.6 REAGENTS AND CONSUMABLES — ADVERSE INCIDENT REPORTING

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables are investigated and reported to the manufacturer and appropriate authorities, as required.

5.3.2.7 REAGENTS AND CONSUMABLES — RECORDS

Records are maintained for each reagent and consumable that contributes to the performance of examinations. These records include but not limited to the following:

a) Identity of the reagent or consumable.

b) Manufacturer's name and batch code or lot number.

c) Contact information for the supplier or the manufacturer.

d) Date of receiving, the expiry date, date of entering service and, where applicable, the date the material was taken out of service.

e) Condition when received (e.g., acceptable or damaged).

f) Manufacturer's instructions

g) Records that confirmed the reagents or consumables initial acceptance for use.

h) Performance records that confirm the reagents or consumables ongoing acceptance for use.

Where the laboratory uses reagents prepared or completed in-house, the records include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.

Refer to SOP for Purchase and inventory PRL-MGT-006 and

Resource Management Manual PRL-RMM-001

5.4 PRE-EXAMINATION PROCESS

The laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.

5.4.2 INFORMATION FOR PATIENTS AND USERS

The laboratory has information available for patients and users of the laboratory services. The information includes as appropriate:

a) The location of the laboratory.

b) Types of clinical services offered by the laboratory including examinations referred to other laboratories.

c) Opening hours of the laboratory.

d) The examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values.

e) Instructions for completion of the request form.

f) Instruction for preparation of the patient.

g) Instructions for patient-collected samples.

h) Instructions for transportation of samples, including any special handling needs.

i) Any requirements for patient consent (e.g., consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed).

j) The laboratory's criteria for accepting and rejecting samples.

k) A list of factors known to significantly affect the performance of the examination or the interpretation of the results.

l) Availability of clinical advice on ordering of examinations and on interpretation of examination results.

m) The laboratory's policy on protection of personal information.

n) The laboratory's complaint procedure.

The laboratory has information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. The importance of provision of patient and family information, where relevant (e.g., for interpreting genetic examination results), is explained to the patient and user.

5.4.3 REQUEST FORM INFORMATION

The request form allows space for the inclusion of, but not limited to, the following:

a) Patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier.

b) Name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details.

c) Type of primary sample

d) Examinations requested.

e) Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes.

f) Date and, where relevant, time of primary sample collection.

g) Date and time of sample receipt.

NOTE: The laboratory has a documented procedure concerning verbal requests for examinations that includes, providing confirmation by request form within a given time. The laboratory is willing to cooperate with users or their representatives in clarifying the user's request.

Refer to clients' manual PRL-CLM- 001

5.4.4 PRIMARY SAMPLE COLLECTION AND HANDLING

The laboratory has documented procedures for the proper collection and handling of primary samples.

The documented procedures are available to those responsible for primary sample collection whether the collectors are laboratory staff.

NOTE: All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at the laboratory with a request form and willingly submits to the usual collecting procedure, for example, venepuncture. Patients in a hospital bed should normally be given the opportunity to refuse.

In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected.

5.4.4.2 INSTRUCTIONS FOR PRE-COLLECTION ACTIVITIES

The laboratory's instructions for pre-collection activities include the following:

a) Completion of request form or electronic request.

b) Preparation of the patient (e.g., instructions to caregivers, phlebotomists, sample collectors and patients).

c) Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives.

d) Special timing of collection, where needed.

e) Clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g., history of administration of drugs).

5.4.4.3 INSTRUCTIONS FOR COLLECTION ACTIVITIES

The laboratory's instructions for collection activities include the following:

a) Determination of the identity of the patient from whom a primary sample is collected.

b) Verification that the patient meets pre-examination requirements [e.g., fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.].

c) Instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives.

d) In situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions are determined and communicated to the appropriate clinical staff.

e) Instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected.

f) Recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time.

g) Instructions for proper storage conditions before collected samples are delivered to the laboratory.

h) Safe disposal of materials used in the collection.

5.4.5 SAMPLE TRANSPORTATION

The laboratory's instructions for post-collection activities include packaging of samples for transportation. The laboratory has a documented procedure for monitoring the transportations of samples to ensure they are transported:

a) Within a time, frame appropriate to the nature of the requested examinations and the laboratory discipline concerned.

b) Within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples.

c) In a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

Refer to client's manual PRL-CLM- 001

5.4.6 SAMPLE RECEPTION

The laboratory's procedure for sample reception ensures that the following conditions are met.

a) Samples are unequivocally traceable, by request and labelling, to an identified patient or site.

b) Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.

c) Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.

d) All samples received are recorded in LIMS. The date and time of receipt and/or registration of samples is recorded.

The identity of the person receiving the sample is also recorded.

e) Authorized personnel evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).

f) There are instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.

All portions of the primary sample are unequivocally traceable to the original primary sample.

5.4.7 PRE-EXAMINATION HANDLING, PREPARATION AND STORAGE

The laboratory has procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage. Laboratory procedures include time limits for requesting additional examinations or further examinations on the same primary sample.

Refer to:

- **Resource management manual PRL-RMM-001 and**
- **Clients' Manual PRL-CLM-001**

5.5 EXAMINATION PROCESSES

5.5.1 SELECTION, VERIFICATION AND VALIDATION OF EXAMINATION PROCEDURES

The laboratory selects examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes is recorded. The specified requirements (performance specifications) for each examination procedure relate to the intended use of that examination.

NOTE: Preferred procedures are those specified in the instructions for use of in vitro medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines, or national or regional regulations.

5.5.1.2 VERIFICATION OF EXAMINATION PROCEDURES

Validated examination procedures used without modification are subjected to independent verification by the laboratory before being introduced into routine use.

The laboratory obtains information from the manufacturer/method developer for confirming the performance characteristics of the procedure. The independent verification by the laboratory confirms, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process are those relevant to the intended use of the examination results.

The laboratory documents the procedure used for the verification and record the results obtained. Staff with the appropriate authority reviews the verification results and record the review.

5.5.1.3 VALIDATION OF EXAMINATION PROCEDURES

The laboratory validates examination procedures derived from the following sources:

a) Non-standard methods.

b) Laboratory designed or developed methods.

c) Standard methods used outside their intended scope.

d) Validated methods subsequently modified. The validation is as extensive as is necessary and confirm, through the provision of objective evidence (in the

form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.

NOTE: Performance characteristics of an examination procedure should include consideration of : measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity.

The laboratory documents the procedure used for the validation and record the results obtained. Staff with the authority reviews the validation results and record the review. When changes are made to a validated examination procedure, the influence of such changes is documented and, when appropriate, a new validation is carried out.

Refer to Operational Procedure Manual PRL-OPM-001

5.5.1.4 MEASUREMENT UNCERTAINTY OF MEASURED QUANTITY VALUES

The laboratory determines measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples.

The laboratory defines the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.

NOTE: The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of the measured value.

Measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions that include as many routine changes as

reasonably possible in the standard operation of a measurement procedure, e.g., changes of reagent and calibrator batches, different operators, scheduled instrument maintenance.

Examples of the practical utility of measurement uncertainty estimates might include confirmation that patients' values meet quality goals set by the laboratory and meaningful comparison of a patient value with a previous value of the same type or with a clinical decision value.

The laboratory considers measurement uncertainty when interpreting measured quantity values. Upon request, the laboratory makes its estimates of measurement uncertainty available to laboratory users. Where examinations include a measurement step but do not report a measured quantity value, the laboratory calculates the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.

Refer to Operational Procedure Manual PRL-OPM-001

5.5.2 BIOLOGICAL REFERENCE INTERVALS OR CLINICAL DECISION VALUES

The laboratory defines the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users. When a biological reference interval or decision value is no longer relevant for the population served, appropriate changes are made and communicated to the users. When the laboratory changes an examination procedure or pre-examination procedure, the laboratory reviews associated reference intervals and clinical decision values.

Refer to:

- **Clients' manual PRL CLM 001 and**
- **Operational Procedure Manual PRL OPM 001**

5.5.3 DOCUMENTATION OF EXAMINATION PROCEDURES

Examination procedures are documented. They are written in a language commonly understood by the staff in the laboratory and be available in appropriate locations.

NOTE: Working instructions that summarize key information are acceptable for use as a quick reference at the workbench, provided that a full documented procedure is available for reference.

Information from product instructions for use may be incorporated into examination procedures by reference. All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, are subject to document control.

In addition to document control identifiers, documentation includes, when applicable to the examination procedure, the following:

a) Purpose of the examination.

b) Principle and method of the procedure used for examinations.

c) Performance characteristics.

d) Type of sample (e.g., plasma, serum, urine).

e) Patient preparation.

f) Type of container and additives.

g) Required equipment and reagents.

h) Environmental and safety controls.

i) Calibration procedures (metrological traceability.

j) Procedural steps.

k) Quality control procedures.

l) Interferences (e.g., lipemia, haemolysis, bilirubinaemia, drugs) and cross reactions.

m) Principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values.

n) Biological reference intervals or clinical decision values.

o) Reportable interval of examination results.

p) Instructions for determining quantitative results when a result is not within the measurement interval.

q) Alert/critical values, where appropriate.

r) Laboratory clinical interpretation.

s) Potential sources of variation.

t) References.

5.6 ENSURING QUALITY OF EXAMINATION RESULTS

The laboratory ensures the quality of examinations by performing them under defined conditions. Appropriate pre- and post-examination processes are implemented.

The laboratory does not fabricate any results.

5.6.2 QUALITY CONTROL

The laboratory has designed quality control procedures that verify the attainment of the intended quality of results.

5.6.2.2 QUALITY CONTROL MATERIALS

The laboratory uses quality control materials that react to the examining system in a manner as close as possible to patient samples. Quality control materials are periodically examined with a frequency that is based on the

stability of the procedure and the risk of harm to the patient from an erroneous result.

5.6.2.3 QUALITY CONTROL DATA

The laboratory has a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results are rejected, and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory also evaluates the results from patient samples that were examined after the last successful quality control event.

Quality control data is reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded.

Refer to Operational Procedure Manual PRL-OPM-001

5.6.3 INTERLABORATORY COMPARISONS

5.6.3.1 PARTICIPATION

The laboratory participates in an interlaboratory comparison program(s) (such as an external quality assessment program or proficiency testing program) appropriate to the examination and interpretations of examination results.

The laboratory monitors the results of the interlaboratory comparison program(s) and participates in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

The laboratory established a documented procedure for interlaboratory comparison participation that includes defined responsibilities and

instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison program.

Interlaboratory comparison program(s) chosen by the laboratory provides clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures.

5.6.3.2 ALTERNATIVE APPROACHES

Whenever an interlaboratory comparison is not available, the laboratory develops other approaches and provides objective evidence for determining the acceptability of examination results. Whenever possible, this mechanism utilizes appropriate materials. **The laboratory does not participate in alternative approaches.**

Examples of such materials may include:

— Certified reference materials.

— Samples previously examined.

— Material from cell or tissue repositories.

— Exchange of samples with other laboratories.

— Control materials that are tested daily in interlaboratory comparison program.

5.6.3.3 ANALYSIS OF INTERLABORATORY COMPARISON SAMPLES

The laboratory integrates interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. Interlaboratory comparison samples are examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.

The laboratory does not communicate with other participants in the interlaboratory comparison program about sample data until after the date

for submission of the data. The laboratory does not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this can routinely be done with patient samples.

5.6.3.4 EVALUATION OF LABORATORY PERFORMANCE

The performance in interlaboratory comparisons is reviewed and discussed with relevant staff. When predetermined performance criteria are not fulfilled (i.e., nonconformities are present), staff participate in the implementation and recording of corrective action. The effectiveness of corrective action is monitored. The returned results are evaluated for trends that indicate potential nonconformities and preventive action are taken.

Refer to Operational Procedure Manual PRL-OPM-001

5.6.4 COMPARABILITY OF EXAMINATION RESULTS

There is a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.

In the case of measurement results that are metrologically traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable.

The laboratory notifies users of any differences in comparability of results and discusses any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand and when examination methods are changed.

The laboratory documents, records and as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified are acted upon and records of actions retained.

Refer to Operational Procedure Manual PRL-OPM-001

5.7 POST EXAMINATION PROCESSES

5.7.1 REVIEW OF RESULTS

The laboratory has procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.

5.7.2 STORAGE, RETENTION AND DISPOSAL OF CLINICAL SAMPLES

The laboratory has a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. The laboratory defines the length of time clinical samples are to be retained.

Retention time is defined by the nature of the sample, the examination and any applicable requirements.

Refer to Operational Procedure Manual PRL-OPM-001

5.8 REPORTING OF RESULTS

The results of each examination are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures. The laboratory defines the format and medium of the report (i.e., electronic or paper) and the way it is to be communicated from the laboratory.

The laboratory has a procedure to ensure the correctness of transcription of laboratory results. Reports include the information necessary for the interpretation of the examination results. The laboratory has a process for

notifying the requester when an examination is delayed that could compromise patient care.

5.8.2 REPORT ATTRIBUTES

The laboratory ensures that the following report attributes effectively communicate laboratory results and meet the users' needs:

a) Comments on sample quality that might compromise examination results.

b) Comments regarding sample suitability with respect to acceptance/rejection criteria.

c) Critical results, where applicable.

d) Interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results in the final report.

5.8.3 REPORT CONTENT

The report includes, but not be limited to, the following:

a) A clear, unambiguous identification of the examination including, where appropriate, the examination procedure.

b) The identification of the laboratory that issued the report.

c) Identification of all examinations that have been performed by a referral laboratory,

d) Patient identification and patient location on each page.

e) Name or another unique identifier of the requester and the requester's contact details.

f) Date of primary sample collection (and time, when available and relevant to patient care).

g) Type of primary sample.

h) Measurement procedure, where appropriate.

i) Examination results reported in SI units, units traceable to SI units, or other applicable units.

j) Biological reference intervals, clinical decision values, or diagrams/monograms supporting clinical decision values, where applicable.

k) Interpretation of results, where appropriate.

l) Other comments such as cautionary or explanatory notes (e.g., quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure).

m) Identification of examinations undertaken as part of a research or development program and for which no specific claims on measurement performance are available.

n) Identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed).

o) Date of the report, and time of release (if not contained in the report, readily available when needed);

p) Page number to total number of pages (e.g., "Page 1 of 5", "Page 2 of 5", etc.).

5.9 RELEASE OF RESULTS

The laboratory established documented procedures for the release of examination results, including details of who may release results and to whom. The procedures ensure that the following conditions are met.

a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.

b) When examination results fall within established "alert" or "critical" intervals: — A physician (or other authorized health professional) is notified

immediately [this includes results received on samples sent to referral laboratories for examination; — records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.

c) Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.

d) When results are transmitted as an interim report, the final report is always forwarded to the requester.

e) There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally shall be followed by a written report. There are records of all oral results provided.

5.9.3 REVISED REPORTS

When an original report is revised there are written instructions regarding the revision so that:

a) The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report.

b) The user is made aware of the revision.

c) The revised record shows the time and date of the change and the name of the person responsible for the change.

d) The original report entries remain in the record when revisions are made.

Results that have been made available for clinical decision making and revised are retained in subsequent cumulative reports and clearly identified as having been revised. When the reporting system cannot capture amendments, changes or alterations, a record of such is kept.

5.10.1 LABORATORY INFORMATION SYSTEM

The laboratory has access to the data and information needed to provide a service which meets the needs and requirements of the user. The laboratory has a documented procedure to ensure that the confidentiality of patient information is always maintained.

5.10.2 AUTHORITIES AND RESPONSIBILITIES

The laboratory ensures that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care. The laboratory defines the authorities and responsibilities of all personnel who use the system, those who:

a) Access patient data and information.

b) Enter patient data and examination results.

c) Change patient data or examination results.

d) Authorize the release of examination results and reports.

5.10.3 INFORMATION SYSTEM MANAGEMENT

The system (Skylims) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information are:

a) Validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation.

b) Documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users.

c) Protected from unauthorized access.

d) safeguarded against tampering or loss.

e) Operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription.

f) Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions.

g) In compliance with national or international requirements regarding data protection. The laboratory verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g., computer systems, fax machines, e-mail, website, personal web devices).

When a new examination or automated comments are implemented, the laboratory verifies that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory has documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service. When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management is responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.

Refer to Resource Management Manual PRL-RMM-001

Version review history table

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

ACKNOWLEDGEMENT OF READING FORM

My signature confirms that I have read and understood the contents of this document.

Name	Signature	Date