QUALITY MANUAL

SAIDEEP
HEALTHCARE & RESEARCH PVT. LTD.

Saideep Healthcare & Research Pvt Ltd

Viraj Estate, Yashwant Colony, Near DSP Chowk,

Ahmednagar, Maharashtra - 414003

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RELEASE AUTHORISATION

Quality Manual is released under the authority of

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Lab Director

and is the property of

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Signature and Date:

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Date			

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AMENDMENT SHEET

Amend No.	Page No.	Section/Clause No./ Para / line (as Applicable)	Date of Amendment	Amendment made	Reasons for amendment	Sign of Q. Mgr.

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INTRODUCTION

The Quality Manual describes Quality Management System (QMS) of Laboratory. It explains the ability of the Laboratory to consistently provide services that meet applicable accreditation requirements and to operate effectively to maximize quality output. The Quality Manual is prepared, reviewed, approved and issued in accordance with International Standard ISO 15189:2012 'Medical Laboratories - Requirements for quality and competence' and NABL documents as given below:

NABL Doc. No.	Title
NABL 112	Specific criteria *for* Accreditation of Medical Laboratories
NABL 131	Terms & conditions for maintaining NABL accreditation
NABL 133	NABL guide lines for accredited laboratories for use of NABL Logo
NABL 141	Guidelines for estimation and expression of uncertainty in measurement
NABL 142	Policy on calibration & traceability of measurements
NABL 153	Application form for Medical Laboratories
NABL 160	Guide for preparing a quality manual
NABL 161	Guide for internal audit & management review for laboratories
NABL 162	Guide lines for proficiency testing program for testing and calibration laboratories
NABL 163	Policies & procedures for inter-laboratory comparisons and/or proficiency testing
NABL 209	Pre- assessment guidelines and forms
NABL 216	Policy & procedures for dealing with Adverse decisions
NABL 217	Assessment Forms and Checklist (based on ISO 15189:2012)

Quality Manual contains documented statements of quality policy and quality objectives of Lab, which have been designed to provide reasonable assurances of effective planning, operation, and control of key QMS processes.

Quality Manual is the top tier of our documentation system. It is a policy guide for Laboratory quality procedures and is designed to fulfill the requirements for a documented quality system. The manual describes the procedures for operating and maintaining quality management system, and demonstrates that each aspect of the quality system is based on the requirements of ISO 15189:2012 and NABL 112 Guidelines.

It is supported by Quality System Procedures (QSPs) and Standard Operating Procedures (SOPs) which are the second tier of our Quality System. The QSPs/SOPs include management and quality system procedures. The third tier of the documentation system consists of work instructions, logbooks, forms, etc. and other specifications developed at each functional area. The fourth tier of the documentation system consists of equipment manuals, kit inserts, etc.

The manual is made accessible to all lab personnel, ensuring full understanding of, and commitment to, quality. The quality policies and procedures set out in this manual are mandatory to be followed by all lab personnel. The Quality Manual is reviewed once every year or as and when required.

1. SCOPE

The Laboratory offers wide range of routine and specialized tests for screening, diagnosis and monitoring of various diseases/disorders. The policy document covers the following sections of laboratory for the purpose of accreditation as per ISO 15189:2012 and its implementation (Annexure-01). The different sections in the laboratory are:

- Clinical Biochemistry and Immunoassay
- Hematology
- Clinical Pathology
- Serology
- Microbiology

2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- 42 CFR Part 493
- 21 CFR Part 58
- 22 CFR Part 1910
- 21 CFR Part 11
- ISO/IEC Guide 2:2004- Standardization and related activities – General Vocabulary
- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.
- NABL 112 and other NABL documents.
- ISO15189:2012 Medical Laboratories-Particular requirements for quality and competence.

3. TERMS AND DEFINITIONS, ABBREVIATIONS AND DISTRIBUTION

QM uses internationally recognized terms, vocabulary and definitions given in applicable International Standards.

Definitions

3.1

Accreditation: procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks.

3.2

Alert interval/ Critical interval: Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death.

NOTE 1 The interval may be open ended, where only a threshold is defined.

NOTE 2 The laboratory determines the appropriate list of alert tests for its patients and users.

3.3

Automated selection and reporting of results: Process by which patient examination results are sent to the laboratory information system and compared with laboratory-defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention.

3.4

Biological reference interval

Reference interval

Specified interval of the distribution of values taken from a biological reference population

Eg: The central 95 % biological reference interval for sodium ion concentration values in serum from a population of presumed healthy male and female adults is 135 mmol/l to 145 mmol/l.

NOTE 1 A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

NOTE 2 A reference interval can depend upon the type of primary samples and the examination procedure used.

NOTE 3 in some cases, only one biological reference limit is important, for example, an upper limit, x, so that the corresponding biological reference interval would be less than or equal to x.

NOTE 4 Terms such as 'normal range', 'normal values', and 'clinical range' are ambiguous and therefore discouraged.

3.5

Competence

Demonstrated ability to apply knowledge and skills

NOTE: The concept of competence is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents.

[ISO 9000:2005, definition 3.1.6]

3.6

Documented procedure

Specified way to carry out an activity or a process that is documented, implemented and maintained

NOTE 1 The requirement for a documented procedure may be addressed in as single document or by more than one document.

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.5.

3.7

Examination

Set of operations having the object of determining the value or characteristics of a property

NOTE 1 in some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements.

NOTE 2 Laboratory examinations that determine a value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

NOTE 3 Laboratory examinations are also often called assays or tests.

3.8

Inter-laboratory comparison

Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[ISO/IEC 17043:2010, definition 3.4]

3.9

Laboratory coordinator

Person(s) with responsibility for, and authority over, a laboratory

NOTE 1 for the purposes of this International Standard, the person or persons referred to are designated collectively as laboratory coordinator.

NOTE 2 National, regional and local regulations may apply with regard to qualifications and training.

3.10

Laboratory management

Person(s) who direct and manage the activities of a laboratory

NOTE The term 'laboratory management' is synonymous with the term 'top management' in ISO 9000:2005.

3.11

Medical laboratory

Clinical laboratory

Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

NOTE : These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.

3.12

Nonconformity

Nonfulfillment of a requirement [ISO 9000:2005, definition 3.6.2].

NOTE Other terms frequently used include: accident, adverse event, error, event, incident, and occurrence.

3.13

Point-of-care testing /POCT /Near-patient testing

Testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

[ISO 22870:2006, definition 3.1]

3.14

Post-examination processes

Post-analytical phase

Processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results

3.15

Pre-examination processes

Pre-analytical phase

Processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins.

3.16

Primary sample

Specimen

Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

NOTE 1 Global Harmonization Task Force (GHTF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.

NOTE 2 In some ISO and CEN documents, a specimen is defined as “a biological sample derived from the human body”.

NOTE 3 In some countries, the term “specimen” is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.

3.17

Process

Set of interrelated or interacting activities which transform inputs into outputs

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.1.

3.18

Quality

Degree to which a set of inherent characteristics fulfils requirements

NOTE 1 The term “quality” can be used with adjectives such as poor, good or excellent.

BNOTE 2 “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.

[ISO 9000:2005, definition 3.1.1]

3.19

Quality indicator

Measure of the degree to which a set of inherent characteristics fulfils requirements

NOTE 1 Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale.

NOTE 2 Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.

EXAMPLE If the requirement is to receive all urine samples in the laboratory uncontaminated, the number of contaminated urine samples received as a % of all urine samples received (the inherent characteristic of the process) is a measure of the quality of the process.

3.20

Quality management system

Management system to direct and control an organization with regard to quality

NOTE 1 The term "quality management system" referred to in this definition relates to general management activities, the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement.

NOTE 2 Adapted from ISO 9000:2005, definition 3.2.3.

3.21

Quality policy

Overall intentions and direction of a laboratory related to quality as formally expressed by laboratory management

NOTE 1 Generally the quality policy is consistent with the overall policy of an organization and provides a framework for setting quality objectives.

NOTE 2 Adapted from ISO 9000:2005, definition 3.2.4

3.22

Quality objective

Something sought, or aimed for, related to quality

NOTE 1 Quality objectives are generally based on the laboratory's quality policy.

NOTE 2 Quality objectives are generally specified for relevant functions and levels in the organization.

NOTE 3 Adapted from ISO 9000:2005, definition 3.2.5.

3.23

Referral laboratory

External laboratory to which a sample is submitted for examination

NOTE A referral laboratory is one to which laboratory management chooses to submit a sample or sub-sample for examination or when routine examinations cannot be carried out. This differs from a laboratory that may include public health, forensics, tumour registry, or a central (parent) facility to which submission of samples is required by structure or regulation.

3.24

Sample

One or more parts taken from a primary sample

For eg: A volume of serum taken from a larger volume of serum.

3.25

Turnaround time

Elapsed time between two specified points through pre-examination, examination and post-examination processes

3.26

Validation

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 Adapted from ISO 9000:2005, definition 3.8.5.

3.27

Verification

Confirmation, through provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 The term “verified” is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

— performing alternative calculations,

— comparing a new design specification with a similar proven design specification,

— undertaking tests and demonstrations, and

— reviewing documents prior to issue.

(ISO 9000:2005, definition 3.8.4)

Abbreviations

BRI	Biological Reference Interval
CAP	College of American Pathologist
CAPA	Corrective and Preventive Action
CLIA	Clinical Lab Improvement Act
CME	Continuous Medical Education
EQAS	External Quality Assurance Scheme
HIV	Human Immuno-Deficiency Virus
HBsAg	Hepatitis B Virus Surface Antigen
HCV	Hepatitis C Virus
IQ	Installation Qualification
IQC	Internal Quality Control
ILC	Inter Laboratory Comparison
ISO	International Organization for Standardization
IEC	International Electro Technical Commission
LIS	Laboratory Information System
NABL	National Accreditation Board for Testing and Calibration Laboratory
OQ	Operation Qualification
PQ	Performance Qualification

PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
SOP	Standard Operating Procedures

SRS	Service Request Slip
TAT	Turn Around Time
UV-IFCC	Ultra Violet-International Federation of Clinical Chemistry
WI	Work Instructions
%CV	Percent Coefficient of Variance

Copy	Name/Designation of the holder of controlled copy	Number of copies

Distribution

Quality Manager has the master copy; a copy is photocopied from the master copy and is numbered and distributed to Laboratory by Quality Manager after stamping as "CONTROLLED COPY".
All newly joined lab personnel should read and understand the quality manual. A copy of the QM is

made available to the entire Lab staff as hard copy.
If a copy of QM is required for regulatory submission to any agencies outside Lab, the same is photocopied from the master copy and stamped as "UNCONTROLLED COPY" and signed with date in the right corner of the footer and released by Quality Manager.
Whenever the revision occurs, the superseded copy will be collected from the Lab/Lab Director by Quality Manager. The revised copies are issued and records are maintained for the same.

1	Quality Manager	1+ 1 Soft copy (Master Copy)
2	Lab Director	1
3	Lab	1

4. MANAGEMENT REQUIREMENTS

4.1 ORGANIZATION AND MANAGEMENT RESPONSIBILITY

4.1.1 Organization

4.1.1.1 **General: - Saideep Healthcare & Research Pvt Ltd** (hereinafter in this manual referred to as "") established on 1 January 2017, has systematically adapted and implemented the requirements of International Standard ISO15189:2012 & NABL 112 and the user needs when carrying out work at its permanent facility. The laboratory does not have any mobile or temporary facilities for testing.

SH is a medium sized lab with approx. 1100 sq. ft area on first floor.

Address: Saideep Healthcare & Research Pvt Ltd

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Ahmednagar, Maharashtra - 414003

All sections of the laboratory remain functional 24/7 including Sunday.

The lab has no Collection centers, besides the main lab.

Legal Entity: SH, is an independent Clinical Pathology Lab with legal entity and is legally responsible for all its laboratory activities. It is a registered under the Shop Act vide certificate no. 2220700316119119 dated 12 Feb 2019.

4.1.1.2 Ethical conduct: The laboratory management has defined Ethics (Annexure-04) to be followed in lab arrangements in place through a well-defined procedure to ensure the following:

a) there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity at all times through transparency in all its operations;

b) management and personnel are free from any internal or external undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work.

c) Lab does not use samples for purpose other than those requested. In case they are used they are rendered anonymous or pooled. Adequate training (refer section 5.1) is provided to all staff and supervision appropriate to their experience and level of responsibilities by competent persons to ensure that staff handles and disposes human samples, according to relevant legal requirements;

d) an undertaking in the form of "Confidentiality Undertaking" is taken from all employees at the time of recruitment and joining the organization to maintain confidentiality. It is maintained with Quality Manager.

4.1.1.3 Laboratory Director

Laboratory Director, has the necessary qualification and vast experience in diagnostic field and training to meet the needs of user and delegated responsibilities for the services provided. Laboratory Director has the necessary competence, authority and resources in order to fulfil the requirements of ISO 15189:2012 and NABL 112.

The Laboratory Director has delegated selected duties and responsibilities to Pathologist/Quality Manager; however the laboratory Director maintains the ultimate responsibility for the overall operation and administration of the laboratory.

The responsibilities of the Laboratory Director include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services

offered by the laboratory. The duties and responsibilities of Laboratory Director primarily includes the following:

a) provide effective leadership of the medical laboratory services, including budget planning and financial management, in accordance with organizational assignment of such responsibilities;

b) relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community and the patient population served and the providers of formal agreements when required;

c) ensure 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) ensure the implementation of the quality policy by monitoring the Quality Objectives;

e) implement a safe laboratory environment in compliance with good practice and applicable requirements;

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

g) ensure the provision of the clinical advice with respect to the choice of examinations, use of the services and interpretation of examination results;

h) select and monitor laboratory suppliers ;

i) select referral laboratories and monitor the quality of their services;

j) provide professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;

k) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

l) monitor all works performed in the laboratory to determine that clinically relevant information is being generated;

m) address any complaint, request or suggestion from staff and / or user of the laboratory services;

n) design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;

o) involve and support Lab related all activities.

4.1.2 Management Responsibility

4.1.1.1 Management commitment

Laboratory management provides evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

a) communicating to laboratory personnel the importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements;

b) establishing the quality policy (see 4.1.2.3);

c) ensuring that quality objectives and planning are established (see 4.1.2.4);

d) defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5);

e) establishing communication processes (see 4.1.2.6);

f) appointing a quality manager (see 4.1.2.7);

g) conducting management reviews (see 4.15);

h) ensuring that all personnel are competent to perform their assigned activities (see 5.1.6);

i) ensuring availability of adequate resources (see 5.1, 5.2 and 5.3) during budget planning to enable the proper conduct of pre-examination, examination and post-examination activities (see 5.4, 5,5, and 5.7).

4.1.1.2 Needs of users

Laboratory management ensures that laboratory services, including appropriate advisory and interpretative services, meet the needs of its users through well-established service

agreements. The service agreements are reviewed every year for its appropriateness after discussion with physicians. Good and appropriate lab services are provided through well laid down QSPs, SOPs, WIs and validated / verified methods using calibrated instruments, qualified, trained and competent manpower, quality techniques and good clinical laboratory practices. Complaints and feedback from patients and its users are obtained regularly for improvement of lab services.

4.1.1.3 Quality policy

Laboratory management has defined the intent of its quality management system in a quality policy:

a. Laboratory endeavors to provide cost effective, reliable and accurate laboratory services to all its patients.

b. Lab is committed to highest quality, through well laid down procedures, validated/verified methods using calibrated state of art instruments, standard reagents and kits, qualified and trained manpower, quality techniques and laboratory practices.

c. The Laboratory complies with requirement of recognized standards of lab practices as per ISO 15189:2012 and adheres to national and international standards applicable to Clinical testing laboratory.

d. Laboratory management has established quality objectives which are measurable and consistent with the quality policy and ensures continuous Quality improvement by monitoring IQC/PT results, Quality Indicators, training and upgradation of staff skills and participation in audits.

e. The quality policy is reviewed for continuing suitability and communicated and understood by all employees.

Dr. Sahil Shaikh
Lab Director, SH

4.1.1.4 Quality Objectives and Planning

Laboratory management has established quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

The laboratory management:

a. Identifies, implements, monitors and evaluates the processes needed for robust and world class quality management system throughout the laboratory;
b. Determine and establish the criteria and methods needed to ensure that both the operations and its controls are effective
c. Ensures customer satisfaction by providing accurate, timely and cost effective diagnostic services;
d. Ensure continual review, upgrade and improve our capabilities to provide best services to customers.

Laboratory management ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

EQAS / ILC:
For assuring the quality of test results to get satisfactory performance up to 90% through EQAS/ILC participation

Training:

Saideep Healthcare & Research Pvt. Ltd. arranges continuous training to all staff members of Collection center internally and externally which can be assessed by competency evaluation

Review of documents
All the documentation procedures and testing methods are reviewed once in a year.

TAT
Saideep Healthcare & Research Pvt. Ltd. can generate the reports with in a defined TAT and will be monitored daily and monthly and evaluated against its target.

Amendment Reports:
The amendment report is clearly identified with a note and issued within a defined TAT and monitored.

Rejection samples
All the received samples are verified, if any sample is rejected inform to the ward, doctor & patient in a timely manner which are documented and monitored.

4.1.1.5 Responsibility, authority and interrelationships

Laboratory management has defined and documented the responsibilities, authorities and interrelationships in job description and Organization chart (Annexure 05) and also communicated within the laboratory organization. Lab management has identified and appointed person(s) responsible for each laboratory function and deputies for key managerial and technical personnel.

In the absence of	Deputy assigned
Lab Director/ Pathologist	Quality Manager

4.1.1.6 Communication

Laboratory management ensures effective communication processes between the various departments of laboratory through intercom, emails, data sharing by restricted access of common network server, verbal and/or written communication, etc. Lab also holds meetings with the staff of laboratory, once a year and as and when required, on suggestions and

effectiveness of the laboratory's current pre-examination, examination and post-examination processes and quality management system. Records have been kept of issues discussed in communications and meetings.

4.1.1.7 Quality Manager

Laboratory management has appointed a Quality Manager who, irrespective of other responsibilities of Pathologist, has responsibility and authority which includes:

a) ensuring that processes needed for the quality management system are developed, implemented, and maintained through a well-defined written QSPs/SOPs and Work Instructions (WI);

b) the findings raised / improvements suggested by Quality Manager are reported to Lab Director, at the level at which decisions are made on laboratory policy, objectives, resources and on the performance of the quality management system;

c) ensuring the promotion of awareness of users' needs through continuous improvement plans throughout the laboratory organization.

Related Procedures/Manuals/Forms

- **SH/QSP/08**

4.2 QUALITY MANAGEMENT SYSTEM

4.2.1 General Requirements

The laboratory has established, documented its policies procedures and instructions as per the requirements of ISO 15189:2012 and communicates to all relevant personnel. Lab also ensures that the documents are understood and implemented by providing necessary induction / refresher / continuous trainings to all personnel.

The documentation hierarchy practiced in the laboratory is as follows.

- Level 1 Document – Quality Manual
- Level 2 Document – Quality System Procedures / Standard Operating Procedures
  Sample Collection Manual/Safety Manual
- Level 3 Document – Forms / Logbooks/ work instructions, etc.
- Level 4 Document – Equipment manuals, kit inserts,

The preparation, review, approval and issue of various documents are addressed in QSP. The laboratory has an established documented, implemented and maintained Quality management system and continually improves its effectiveness in accordance with the requirements of ISO 15189:2012. The quality management system provides for the integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of its users.

The laboratory management:

a) determines the processes needed for the quality management system and ensures their application by establishing procedures (QSPs/SOPs/WIs) throughout the laboratory;
b) determines the sequence and interaction of these processes by developing flowcharts for efficient and smooth functioning.
c) determines the criteria and methods needed to ensure that both the operation and control of these processes are effective through regular monitoring of systems by Quality Manager.
d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
e) monitors and evaluate these processes.
f) implements actions necessary to achieve planned results and continual improvement of these processes through monitoring of quality indicators and regular audits.

4.2.2. Documentation Requirements

4.2.1.1 General

The quality management system documentation includes:

a) Statements of a quality policy (see 4.1.2.3) and quality objectives (see 4.1.2.4);
b) a quality manual (see 4.2.2.2);
c) procedures (QSPs/SOPs / WIs) and records required by this International Standard;
d) documents, and records, determined by the laboratory to ensure the effective planning, operation and control of its processes;
e) copies of applicable regulations, standards and other normative documents.

NOTE: The documentations are in electronic form as well as hard copies and are readily accessible. They are protected from unauthorized changes and undue deterioration by restricted entry and individual password access.

4.2.1.2 Quality Manual

The laboratory has established and maintains a quality manual which includes:

a) the quality policy (4.1.2.3);

b) a description of the scope of the quality management system;

c) a presentation of the organization and management structure of the laboratory and its place in any parent organization (Organization chart, Annexure 04);

d) a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard.

e) a description of the structure and relationships of the documentation used in the quality management system (4.2.1);

f) the documented policies established for the quality management system and reference to the managerial and technical activities that support them.

All laboratory staff has access to and are instructed on the use and application of the quality manual and the referenced documents.

Related Procedures/Manuals/Forms

- **SH/QSP/01**

4.3 DOCUMENT CONTROL

The laboratory controls documents required by the quality management system and ensures that unintended use of any obsolete document is prevented.

To assure consistent quality, written approved procedures are followed for all activities. The Quality Manager is responsible to prepare, issue, distribute, revise and archive the controlled documents.

Appropriate change control procedures are followed for revising existing procedures. It involves preparation and issue by Quality Manager, review and approval by the Lab Director.

A Master list of the quality system document is prepared showing the present status. The controlled copy of the document is marked / identified as “Controlled Copy” by the Quality Manager with a unique number allotted to each recipient. Any “uncontrolled copy” is issued after authorization of Quality Manager.

Quality Manager ensures that superseded documents are withdrawn from all places. Master copy of the same will be retained with obsolete stamp as record and other copies will be discarded. The Quality Manager also ensure that only current documents are in usage and available to concerned personnel in the respective work.

A copy of each of these controlled documents is archived for later reference and must be retained till the next issue becomes obsolete. These controlled documents are maintained as hard copies or as per applied regulations concerning document retention.

Procedures are adopted to ensure that:

a) all documents issued to laboratory personnel as part of the quality management system are reviewed and approved by authorized personnel prior to issue;

b) a list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained by Quality Manager;

c) Quality Manager ensures the availability of current documents at the site of activity.

d) documents are reviewed annually with version upgrade after 20 amendments and revised if necessary and approved by authorized personnel;

e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use;

f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use;

g) laboratory's documentation control system allows for the amendment of documents by authorized personnel only. The procedures and authorities for such amendments are defined, while amendments are clearly marked with sign & date. The amendments are included in the amendment log. The original and amended documents are filed together.

h) procedures are established to describe how changes to documents maintained in computerized systems are to be made and controlled.

All documents relevant to the quality management system are uniquely identified, to include:

a) Name of lab;

b) Document Title and Number

c) Issue No and Date

d) Amendment Number and Date;

e) Page number to total number of pages (e.g. "Page 1 of 5");

f) Prepared by

g) Authority for review, approval and issue;

Related Procedures/Manuals/Forms

- **SH/QSP/01**

4.4 SERVICE AGREEMENTS

4.4.1 Establishment of Service Agreements

SH is a medium sized diagnostic laboratory. The laboratory has documented procedures (Sample Collection Manual) for the establishment and review of agreements for providing medical laboratory services. Each request accepted by the laboratory for examination(s) is considered as an agreement. Procedures are established and documented as SOPs to perform the lab investigations.

Arrangements to provide medical laboratory services takes into account the request, the examination and the report. The arrangement specifies the information needed on the request to ensure appropriate examination and result interpretation. Lab ensures that the following conditions are met when the laboratory enters into an agreement to provide medical laboratory services.

a) the requirements of the lab users, and of the provider of the laboratory services, including the examination processes to be used, are defined, documented and understood.
b) the laboratory has the capability and resources to meet the requirements.
c) laboratory personnel have the skills and expertise necessary for the performance of the intended examinations.
d) examination procedures selected are appropriate and able to meet the users' needs.
e) users of lab services are informed of any deviations from the agreement that impact upon the examination results telephonically followed by emails,
f) users are informed of any work referred by the laboratory to a referral laboratory.

4.4.2 Review of Service Agreements

The Lab Director/ Pathologist /Quality Manager periodically review all aspects of the services required from the laboratory.

When an agreement needs to be amended after laboratory services have commenced, the same agreement review process is repeated and amendments are communicated to all affected parties. Records of these reviews which include changes to the agreement and pertinent discussions are maintained.

Related Procedures/Manuals/Forms

- **SH/MAN/02 -Sample Collection Manual**

4.5 EXAMINATION BY REFERRAL LABORATORIES

4.5.1 Selecting and evaluating referral laboratories and consultants

Saideep Healthcare & Research Pvt. Ltd. has a policy decision undertakes to report only on those tests performed within the laboratory. If applicable, Saideep Healthcare & Research Pvt. Ltd. takes the opinion from the referral laboratory. Saideep Healthcare & Research Pvt. Ltd. has a documented procedure for selection and evaluating referral laboratories.

a) A list of all approved referral laboratories are maintained with the QM. A NABL accredited laboratory is selected as a referral laboratory.

b) Arrangement with referral laboratories are reviewed and evaluated. The referral lab is able to meet the requirements and there are no conflicts of interest.

c) Records of such periodic reviews are maintained.

d) A register is maintained by the laboratory for every test referred to the referral laboratory.

e) The examinations referred to the referral laboratories and also the results are maintained and documented as per the procedure of Saideep Healthcare & Research Pvt. Ltd..

The laboratory has an effective documented procedure for selecting and evaluating referral laboratories. The procedure ensures that the following conditions are met.

a) Lab Director/ Quality Manager, with the advice of users of laboratory services, is responsible for selecting and monitoring the quality of referral laboratories and ensures that the referral laboratory is competent and accredited as per ISO 15189 standards to perform the requested examinations.

b) arrangements with referral laboratories are reviewed and evaluated annually to ensure that the relevant parts of ISO 15189 are met.

c) records of such annual reviews are maintained as per organizational policy.

d) the lab maintains a list of all current referral laboratories that it uses.

e) the lab also maintains a log in software (Mednet) containing the details of all samples that have been referred to referral laboratory. Lab retains an electronic copy of the Referral laboratory report.

4.5.2 Provision of Examination Results

Unless otherwise specified in the agreement, the Lab is responsible for ensuring that examination results of the referral laboratory are provided to the user making the request. The results are provided in their original format which includes the name of the referral laboratory. This reduces turnaround times and transcription errors without altering measurement accuracy and original interpretation. Sometimes the lab transcribes the results in its own format and ensures the user is made aware that the sample has been tested outside. The process is not hindered by commercial or financial considerations.

Related Procedures/Manuals/Forms

- **SH/QSP/02**

4.6 EXTERNAL SERVICES AND SUPPLIES

The laboratory has a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service (see also 5.3).

The laboratory selects and approves suppliers based on vendors ability to provide external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements. Purchasing information describes the requirements for the product or service to be purchased.

The vendors supplies are evaluated for every shipment and vendor evaluations are done annually and approved vendors list is prepared as per their performance. The laboratory conducts vendor evaluation once a year to ensure that purchased services or items consistently meet the stated criteria. A list of selected, approved and evaluated suppliers is maintained in the lab.

Related Procedures/Manuals/Forms

- **SH/QSP/03**

4.7 ADVISORY SERVICES

The Laboratory Director / Pathologist/ Quality Manager/ Senior technical staff regularly communicates with users telephonically/by emails with respect to:

a) advice on choice of examinations and use of the services, including required type/collection procedure of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination.
b) advising on individual clinical cases, if necessary;
c) professional judgments on the interpretation of the results of examinations;
d) promoting the effective utilization of laboratory services;
e) consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.

The lab communicates verbally/telephonically/through emails with users regarding the use of laboratory services and for the purpose of consultation on scientific matters and maintains records of services provided.

Related Procedures/Manuals/Logbooks/Forms

- **SH/Form/08**

4.8 RESOLUTION OF COMPLAINTS

The laboratory has a documented procedure for the collection and management of complaints and /feedback received from users of Lab services. Appropriate corrective and preventive actions are planned, documented and implemented. The review of complaints and feedback are presented in MRM and appropriate CAPA is planned and implemented. All records of complaints, investigations and corrective actions taken by the laboratory are maintained.

Related Procedures/Manuals/Forms

- **SH/QSP/04**

4.9 IDENTIFICATION AND CONTROL OF NONCONFORMITIES

Nonconforming examinations or activities occur in many different areas in the lab and can be identified in many different ways which include interlaboratory comparisons, review of internal quality control charts/ EQAS results, machine downtime, delay in TAT, user complaints, instrument calibrations, inventory management, reporting, laboratory management reviews, etc.

The laboratory has documented procedures for conducting internal audits, quality indicator and potential risks monitoring to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes.

The procedure ensures that:

a) the responsibilities and authorities for handling nonconformities are designated;

b) the immediate actions to be taken and the time limits are defined;

c) the extent of the nonconformity is determined;

d) examinations are halted and reports withheld as necessary;

e) the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting user or authorized individual responsible for using the results is informed;

f) the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary;

g) the responsibility for authorization of the resumption of examinations lies with Lab Director / Pathologist/ Quality Manager;

h) each episode of nonconformity is documented and recorded in NC form (SH/Form/01) and the records are reviewed every month to detect trends and initiate corrective action/preventive action.

i) when it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's

compliance with its own procedures, the laboratory takes action to identify, document and eliminate the cause(s). Corrective/preventive action to be taken is determined and documented (SH/Form/01).

Related Procedures/Manuals/Forms

- **SH/QSP/06**
- **SH/Form/01**

4.10 CORRECTIVE ACTION

Lab takes corrective action to remedy non-conformities that are identified. Procedure for corrective action includes an investigative process to determine the underlying cause or causes of the problem leading to preventive actions wherever appropriate. Decision on the corrective action to be taken is based on the magnitude of the problem and commensurate with the possible risks encountered. Corrective actions are generally required for:

- complaints
- system nonconformities identified by Quality Manager
- machine breakdowns
- IQC, EQAS, ILC outliers
- QSP/SOP deviations

It is the responsibility of the Lab Director/Pathologist/ Quality Manager to:

a) review nonconformities;

b) determine appropriate root causes of nonconformities;

c) evaluate the need for corrective action to ensure that nonconformities do not recur;

d) determine and implement corrective action needed;

e) record the results of corrective action taken (see 4.13);

f) ensure review of the effectiveness of the corrective action taken (see 4.14.5) by Quality Manager.

When the identification of non-conformity or the corrective action investigation casts doubt on compliance with policies and procedures or the quality management system, laboratory management ensures that appropriate areas of activity are audited. The results of corrective action are submitted for laboratory management review.

Related Procedures/Manuals/Forms

- **SH/QSP/06**
- **SH/Form/01**

4.11 PREVENTIVE ACTION

Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). It is an action taken to eliminate the cause of a potential non-conformance which is appropriate to the effects of the potential problems. Procedure for preventive actions may include but may not be limited to:

a) reviewing laboratory data which include IQC results, calibration data, lab procedures, trend and risk analyses of non- conformities and external quality assessment and information to determine where potential nonconformities exist;

b) determining the root cause(s) of potential nonconformities;

c) evaluating the need for preventive action to prevent the occurrence of nonconformities;

d) determining and implementing preventive action needed;

e) recording the results of preventive action taken (see 4.13);

f) reviewing the effectiveness of the preventive action taken.

Related Procedures/Manuals/Forms

- **SH/QSP/06**
- **SH/Form/01**

4.12 CONTINUAL IMPROVEMENT

The laboratory management systematically reviews the quality management systems annually to identify any potential sources of non-conformities, effectiveness of corrective and preventive actions taken and to identify more opportunities for improvements thus ensuring there is continual improvement in the quality management system which includes the pre-examination, examination and post-examination processes. Based on the review of work processes, non-conformities, feedbacks/complaints internal/external audit reports, results of IQC/, EQAS/ILC, risk assessment and monitoring of quality indicators, improvement activities are then developed, documented and implemented, as appropriate at areas of highest priority based on risk assessments.

Laboratory management ensures that the laboratory participates in continual improvement activities which encompass relevant areas and outcomes of patient's safety and care. CME effectiveness are also evaluated periodically. Continual improvement activities may include but not limited to:

- Identification and monitoring of new quality indicators in different areas of lab operations.
- Continuous education by regularly conducting CMEs.
- Periodic refresher trainings on Biosafety and Fire safety.
- Increasing quality goals in terms of lab performance.
- Providing access to suitable educational and training opportunities.

When the continual improvement programme identifies opportunities for improvement, laboratory management addresses them regardless of where they occur. All improvement programmes and related goals are communicated to staff for immediate implementation.

Related Procedures/Manuals/Forms

- **SH/SOP/GEN/03**
- **SH/SOP/GEN/04**

4.13 CONTROL OF RECORDS

Laboratory has developed and implemented procedure for preparation, review, approval, control, distribution, revision and destruction of QSPs/SOPs. The QSP also describes procedure for amendment so as to ensure that the date and, where relevant, the time of amendments to records are captured along with the identity of personnel making the amendments.

The laboratory has also established QSPs for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records. All archival records are stored such that they are readily retrievable. Storage area is access controlled, termite-resistant with protective safe cabinets to archive the records and to any prevent damage, deterioration, loss or unauthorized access. The laboratory retains various records pertaining to the quality management system and examination results in paper as well as electronic form.

Records include the following:

a) supplier selection and performance, and changes to the approved supplier list;
b) staff qualifications, training and competency records;
c) Test request slips;
d) records of receipt of samples in the laboratory;
e) information on reagents and materials used for examinations (e.g. Inventory, lot documentation, certificates of supplies, package inserts);
f) records of receipt of reagents and their shipment condition in the laboratory.
g) laboratory logbooks and forms;
h) instrument printouts and retained data and information in various lab software's and computer's;
i) examination results and reports;
j) instrument maintenance records, including internal and external calibration records
k) calibration functions and conversion factors;

l) quality control records;

m) incident records and action taken;

n) accident records and action taken;

o) risk management records (if available);

p) non-conformities identified and immediate or corrective action taken;

q) preventive action taken;

r) complaints/Feedback and action taken;

s) records of internal and external audits;

t) interlaboratory comparisons/EQAS of examination results;

u) records of quality improvement activities;

v) minutes of meetings that record decisions made about the laboratory's quality management activities;

w) records of management reviews.

These quality and technical records are readily available for review by laboratory management.

Related Procedures/Manuals/Forms

- **SH/QSP/01**

4.14 EVALUATION AND AUDITS

4.14.1 General

The Quality Manager plans and schedules the internal audits to assess the following:

a) that pre-examination, examination and post-examination and supporting processes are as per the relevant SOPs and comply to the ISO 15189:2012, NABL 112 and other applicable guidelines;

b) ensure conformity to the quality management system;

c) continually improve the effectiveness of the quality management system.

d) the results of the internal audit evaluations and improvement activities are included / addressed during the management review (see 4.15).

4.14.2 Periodic Review of Requests, and Suitability of Procedures and Sample Requirements

Lab Director/ Pathologist/Quality Manager review the examinations provided by the laboratory once in a year to ensure that they are clinically appropriate for the requests received.

The laboratory reviews its sample volume, collection device and preservative requirements for blood, urine, and other sample types, as applicable, to ensure that required volume of sample is collected in appropriate vacutainer to ensure integrity and stability of analyte. The same are discussed during lab meetings.

4.14.3 Assessment of User Feedback

The laboratory always encourages both positive and negative feedback from the users (and obtains them regularly. User feedback forms are reviewed regularly to assess whether the lab services provided meet the needs and requirement of users and accordingly appropriate corrective/preventive actions are planned and implemented. Records of the complaints /feedbacks with the appropriate corrective/preventive action are maintained. Feedbacks

along with actions taken are also presented during management review meetings for suggestions and improvements.

4.14.4 Staff Suggestions

Lab management encourages staff to provide suggestions for improvement of the services by mail/verbally/ or remain anonymous by putting in suggestion box . Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of all suggestions/feedbacks and action taken by the management are maintained. Besides this, lab staff are also encouraged to provide additional suggestions if any, for improvement of lab activities, through complaints/feedback forms.

4.14.5 Internal Audit

The Laboratory Director/Pathologist/Quality Manager conducts internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:

a) conform to the requirements of ISO 15189 standard and relevant NABL guidelines and to requirements established by the laboratory, and

b) are implemented, effective, and maintained.

The internal audit is conducted once in a year. The laboratory conducts the scheduled internal audits by covering all the clauses of the ISO15189:2012 and NABL 112. Audits are conducted by Laboratory Director/Pathologist/Quality Manager who are trained to assess the performance of managerial and technical processes of the quality management system and is independent of the function being audited. The audit schedule takes into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined and documented in QSP.

Quality Manager identifies trained auditors and ensures that the audits are conducted with objectivity and impartiality.

The laboratory has documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.13).

Quality Manager ensures appropriate CAPA is promptly undertaken when nonconformities are identified. Corrective action is taken without undue delay to eliminate the causes of nonconformities (see 4.10).

4.14.6 Risk Management

The lab has developed a procedure for risk management (which identifies potential sources of risk associated with various lab activities, evaluates its impact as part of quality indicator monitoring on examination results and plans appropriate corrective and preventive actions to eliminate the risks and prevent a mishap. The risk management plan is reviewed every year.

4.14.7 Quality Indicators

The laboratory identifies potential sources of risk/non- conformities and establishes quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

The process of monitoring quality indicators is planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.

The quality indicators are monitored every month by Quality Manager and a cumulative report is prepared six monthly which is submitted for management review.

Quality indicators on general system aspect of laboratory safety and environment are included for thorough review on Quality systems.

The quality indicators are reviewed continuously and updated according to the system requirements.

4.14.8 Reviews by external organizations

When reviews by external organizations (accreditation assessments, inspection by regulatory agencies/sponsors, and health and safety inspections) indicate that the laboratory has nonconformities or potential nonconformities, the laboratory takes immediate remedies and, as appropriate, corrective action and /preventive action to ensure continuing compliance with the requirements of this ISO 15189:2012 standard. Records of the reviews and of the corrective actions and preventive actions taken are maintained in the laboratory.

Related Procedures/Manuals/Forms

- **SH/QSP/06**
- **SH/Form/01**
- **SH/SOP/GEN/03**
- **SH/SOP/GEN/04**

4.15 MANAGEMENT REVIEW

4.15.1 General

Laboratory management reviews the quality management system of Lab at least once a year to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

4.15.2 Review input

The input to management review includes information from the results of evaluations of the following:

a) the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2);
b) assessment of user feedback (see 4.14.3);
c) staff suggestions (see 4.14.4);
d) internal audits (see 4.14.5);
e) risk management (see 4.14.6)
f) use of quality indicators (see 4.14.7);
g) reviews by external organizations (see 4.14.8);
h) results of participation in interlaboratory comparison programmes (PT/EQA/ILC) (see 5.6.3);
i) monitoring and resolution of complaints (see 4.8);
j) performance of suppliers (see 4.6);
k) identification and control of nonconformities (see 4.9);
l) results of continual improvement (see 4.12) including current status of corrective actions (see 4.10) and preventive actions (see 4.11);
m) follow-up actions from previous management reviews;
n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;
o) recommendations for improvement, including technical requirements.

4.15.3 Review activities

The review analyses the input information for causes of nonconformities, trends and patterns which indicate process problems thus assessing the 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 its users, to the extent possible, is objectively evaluated.

4.15.4 Review output

The output from the management review is incorporated into minutes of the meeting that documents any decisions made and actions taken during management review related to:

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

b) Improvement of services to users;

c) Resource needs.

Findings and actions raised from management reviews are recorded and reported to laboratory staff. Laboratory management ensure that actions arising from management review are completed within a defined timeframe.

Related Procedures/Manuals/Forms

- **SH/QSP/07**

5. TECHNICAL REQUIREMENTS

5.1 PERSONNEL

5.1.1 General

The laboratory has a documented procedure for personnel management and maintains records for all personnel to indicate compliance with ISO 15189:2012, NABL 112 and Lab Policies.

The records are as given below:

- Curriculum Vitae;
- Job descriptions;
- Relevant Educational Certificates;
- Training Records (Internal and External);
- Records of continuing education and achievements;
- Authorization letters for use of instruments;
- Competency evaluations;
- Records of immunization status
- Other records (Medical and untoward incident or accident reports), if any;

5.1.2 Personnel Qualifications

Laboratory management has defined qualifications as per NABL 112 for each position which reflects the appropriate education, training, experience and demonstrated skills needed, and are appropriate to the tasks performed.

Laboratory personnel are appropriately qualified with applicable theoretical & practical background. They are well experienced to provide professional judgements related to interpretation of results in accordance with national, regional and local regulations and professional guidelines, advisory services with reference to examinations, etc.

5.1.3 Job Descriptions

Laboratory management has developed an organizational plan (Annexure-II, III) and documented procedure for personnel policies. Job descriptions have been defined and reviewed when there is a role change for all lab personnel, which describe roles, responsibilities and duties. Laboratory management has authorized personnel to perform particular tasks such as sampling, examination and operation of equipment/laboratory information system after successful evaluation of their competence.

5.1.4 Personnel Introduction to the Organizational Environment

The laboratory management has a well-developed induction training plan. Specific trainings are provided to all new employee pertaining to the role and responsibilities of the individual in the laboratory, health and safety requirements (including fire and emergency), relevant QSPs/SOPs/WIs and guidelines, the specific functional area of the department in which the person will work, the terms and conditions of employment, staff facilities, and occupational health services.

5.1.5 Training

The laboratory imparts continuous training to all personnel which include but not limited to the following areas:

a) quality management system through Manuals;
b) assigned work processes and procedures (QSPs/SOPs and Work Instructions);
c) laboratory Information system;
d) health and safety, including the prevention or containment of the effects of adverse incidents through seminars, trainings organized by the Lab Safety Committee;
e) ethics;

f) confidentiality - Confidentiality of information is maintained by all personnel in Lab. An undertaking in the form of "Confidentiality Undertaking" is taken from all employees at the time of recruitment and joining the organization.

Lab Management also identifies various sources of external training programs as per training needs of the lab personnel. All trainings and assessments are documented in the Training records. Personnel who are undergoing trainings are supervised all times. The effectiveness of all the training programmes is periodically reviewed during competency assessment and appropriate re-trainings are provided if required.

5.1.6 Competence Assessment

Following appropriate training, the laboratory evaluates the competency of all its personnel to perform assigned managerial or technical tasks. Thereafter, reassessment takes place at regular intervals and retraining provided when necessary. Records of competency evaluation of lab personnel are maintained in the laboratory.

Competence of laboratory is assessed by using any combination or all of 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 such as staff shortage, out of range IQC, machine downtime, unavailability of reagents, etc;
f) examination of specially provided samples such as previously examined samples, EQAS samples, interlaboratory comparison materials, or split samples.

5.1.7 Reviews of Staff Performance

Technical competency is evaluated regularly by the Lab Director/ Pathologist/Quality Manager. Lab has a well-defined annual staff performance review system which considers the needs of the laboratory and of the individual in order to maintain/ improve the quality of lab services provided and encourage the productive working relationships.

5.1.8 Continuing Education and Professional Development

Lab Director in consultation with Pathologist identifies the need based on review of QSP/SOP trainings/ nonconformities/ discussions held in lab/during CME and develops a continuing education programme (CME) every year for all lab personnel who participate in managerial and technical processes. All lab personnel participate in continuing education programs and records are maintained. Laboratory Management encourages the staff to attend the external CMEs, refresher trainings, conferences, workshops for regular professional development. Effectiveness of CME/SOP trainings shall be evaluated periodically after CME/QSP/SOP trainings and records maintained.

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 in lab.

All the records are readily available to relevant personnel and include but not be limited to:

a) Educational and professional qualifications;
b) Copy of certificates, when applicable;
c) Previous work experience;
d) Job descriptions;
e) Introduction of new staff to the laboratory environment (Induction training plan);
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 are maintained with safety committee.

k) Immunisation status, when relevant to assigned duties is maintained with Quality Manager.

Related Procedures/Manuals/Logbooks/Forms

- **SH/QSP/08**

5.2 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

5.2.1. General

The laboratory has allocated sufficient space so that lab staff can perform duties without compromising the quality of work, quality control procedures, safety of personnel. The Lab Management has evaluated and determined the sufficiency and adequacy of the space. Lab is an access controlled, medium sized lab diagnostic laboratory on first floor with a carpet area of approximately 1503 sq. ft..

The laboratory has no collection centres. The resources are adequate to support the activities of the laboratory and are maintained in a functional and reliable condition. Similar provisions are made for primary sample collection area.

5.2.2. Laboratory and Office Facilities

The laboratory is well designed for the efficiency of its operation, to optimize the comfort of its occupants and to minimize the risk of injury and occupational illness. It ensures that the following conditions are met:

a) Access to Lab is restricted by access control system to authorised personnel only taking in consideration to safety, confidentiality, quality and prevailing practices.

b) Medical information, clinical samples, and laboratory resources are safeguarded by restricted access to lab and password protected computers / software's in the lab.

c) The laboratory design and environment are suitable for the tasks carried out therein. Laboratory facilities, which include, energy sources, lighting, ventilation, water, waste disposal, and controlled environmental conditions (temperature and humidity), permit correct performance of examinations. The laboratory is daily monitored for temperature and humidity and records are maintained. The lab (Hospital) has two UPS inverter of 120 kVA each.

d) Communication systems which include intercom, emails intranet and direct dialling to mobile phones for selected key personnel, are available within the laboratory and are

appropriate to the size and complexity of the facility and the efficient transfer of messages.

e) Lab is committed to highest standards of safety practices and has set up a Safety Committee. All lab personnel, where appropriate, wear personal protective equipments such as lab coats, gloves, etc. and same is practiced by visitors entering the lab. Measures have been taken to ensure safety by eye wash and fire extinguishers. These safety systems are regularly checked and monitored for their performance (e.g. refilled and periodically checked for fire extinguishers.) Exits are displayed on each floor. Spill kit and First aid kits are readily accessible in the lab. All lab personnel coming in contact with biological samples are immunized with Hepatitis B vaccination. Personnel are periodically instructed for safe working practices and are encouraged to look for hazardous conditions as well as recommend and implement hazard prevention.

5.2.3 Storage Facilities

Lab is well equipped with two 2-8°C refrigerator which is temperature controlled and monitored daily twice to ensure the continuing integrity of sample materials and reagents. Clinical samples and reagents/kits used in examination processes are stored separately in the refrigerator to prevent cross contamination. Reagents requiring storage at room temperature are stored accordingly. Adequate storage space for documents, files, manuals are provided within the lab which are kept locked to prevent unauthorized access.

The lab has a documented procedure for disposal of biomedical waste. It is done by contract Bioclean Systems (India) Pvt Ltd. Registered under Ahmednagar Municipal Corporation.

5.2.4 Staff Facilities

There are clean washrooms, supply of drinking water and cupboards have been provided to all lab employees for storage of personal protective equipment and their belongings. Dining area/meetings area is identified on floor.

5.2.5 Sample Collection Facilities

Sample collection facilities have separate reception/waiting and collection areas with separate toilet for staff and patients. Sample collection area facilitates the sample collection in a manner that does not invalidate the results or adversely affect the quality of the examination. Sample collection facilities spill kits as well as appropriate first aid materials for patients and staff needs. All phlebotomists and personnel coming in contact with blood are immunized with Hepatitis B vaccine and records of immunization status along with their anti HbS titers are kept.

5.2.6 Facility Maintenance and Environmental Conditions

Laboratory premises are maintained in a functional and reliable condition. Work areas are dust free, well lit, ventilated, clean and well maintained through good housekeeping practices. Training is provided to personnel for ensuring good housekeeping and safe disposal and records of daily cleaning are maintained in the lab. The laboratory monitors, controls and records environmental conditions , as required by relevant specifications as it may influence the quality of the sample, results, and/or the health of staff. Attention is paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound 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.

There is effective separation between various laboratory sections in which there are incompatible activities and cross contamination is prevented. The laboratory provides a quiet and uninterrupted work environment in all the sections.

Related Procedures/Manuals/Forms

- **SH/Form/02**
- **SH/Form/03**
- **SH/Form/06**

5.3 LABORATORY EQUIPMENT, REAGENTS, AND CONSUMABLES

5.3.1 Equipment

5.3.1.1 General

The laboratory has a documented procedure for the selection, purchasing and management of equipment. The laboratory is well equipped with state of the art equipments and Lab information system needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage). The laboratory will replace equipment as and when needed to ensure the quality of examination results. The laboratory carries out all the tests at its permanent facility only.

5.3.1.2 Equipment Acceptance Testing

The laboratory has a documented procedure for verifying upon installation and before use that the equipment is capable of achieving the necessary performance (IQ, OQ, PQ) and that it complies with requirements relevant to any examinations concerned. All equipment's are uniquely labelled with identification no. Master list of all equipments which include general as well as specialised, are maintained with calibration and preventive maintenance details and regularly updated in the lab.

5.3.1.3 Equipment Instructions for Use

Equipments are operated at all times by trained and authorized personnel only. current instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) are readily available to laboratory personnel The laboratory follows manufacturer's guideline for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

5.3.1.4 Equipment Calibration and Metrological Traceability

The lab maintains a master list of all equipments used in the lab with updates on calibration and maintenance details. The laboratory has documented procedures for the calibration of all equipments that directly or indirectly affects examination results. The procedure includes:

a) Taking into account 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 as required by the Manufacturer and as per NABL 112.
d) Recording the calibration status and date of recalibration and labels of calibration details are put on all equipments;
e) As and when calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated and all records are kept;
f) Safeguards to prevent adjustments or tampering that might invalidate examination results.

All reference materials used in the lab have metrological traceability to a reference material/reference procedure of the higher metrological order. Documentations of calibration traceability are provided by the manufacturer whose examination systems and calibration procedures are used in the lab without modification. The lab also uses certified reference materials for providing confidence in the tests performed in the lab.

5.3.1.5 Equipment Maintenance and Repair

The laboratory has a well-defined documented plan of preventive maintenance which follows the manufacturer's instructions. All preventive maintenances are planned with prior intimation and spares ordered as required and maintenance conducted.

Equipment are maintained in a safe working condition and in working order which also include safe handling and disposal of chemical and biological materials by authorized persons only. Manufacturers' schedule and /instructions are followed for all equipments.

Whenever equipment is found to be defective, it is taken out of service and clearly labelled as "under maintenance". The laboratory ensures that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The lab has identified referral labs as back up for all its assays in scope, so testing and reporting of samples is not disrupted.

The laboratory takes reasonable measures to decontaminate equipment before service, repair or decommissioning and provide appropriate personal protective equipment and suitable space for repairs. When equipment is removed from the direct control of the laboratory, the laboratory ensures that its performance is verified by running controls/ pre tested sample, performing calibration verification, etc before being returned to laboratory use.

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 and records maintained.

5.3.1.7 Equipment Records

Records are maintained for each equipment that contributes to the performance of Examinations as per the procedure. These records include but not limited to the following:

a) identity of the equipment;
b) manufacturer's name and batch code/lot number;
c) contact information for the supplier or the manufacturer;
d) date of receiving, the expiry date, date of entering into 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 initial acceptance for use (IQ, OQ, PQ);

h) performance records that confirm ongoing acceptance for use;

i) maintenance records which include daily and periodic preventive maintenance log books;

j) calibration records;

k) verification reports;

l) service reports.

5.3.2 Reagents and Consumables

5.3.2.1 General

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

5.3.2.2 Reagents and Consumable - Reception and Storage

Where the laboratory receives the supplies, it verifies through the reagents / kits evaluation checklist, the intactness of packing, shipment conditions and expiry dates to ensure that the purchased items are not damaged or deteriorated. The laboratory follows manufacturer's instructions for safe handling, transport, storage and use of equipment, to prevent its contamination or deterioration.

5.3.2.3 Reagents and Consumables - Acceptance Testing

Each examination kits with changes in reagents or procedure, or a new lot or shipment, is verified for performance before use in examinations as per the QSP. Consumables that can affect the quality of examinations are also verified for performance before use in examinations.

5.3.2.4 Reagents and Consumables - Inventory Management

The laboratory has established an inventory control system as per the QSP for reagents and consumables. The system also records inspected and accepted reagents and consumable and maintains performance records separately. Unacceptable reagent and consumable are returned back to the supplier and records of the same are maintained.

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 maintained in the laboratory for ready reference.

5.3.2.6 Reagents and consumables - Adverse incident reporting

Adverse incidents and accidents that are attributed directly to specific reagents or consumables is investigated, documented 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 /lot number;
c) contact information for the supplier or the manufacturer;
d) date of receiving, the expiry date, date of entering into 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 in Parallel testing logbook.
i) 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. Prepared reagents are also labelled with the details.

Related Procedures/Manuals/Forms

- **SH/QSP/03**

- **SH/Form/04**
- **SH/Form/05**

5.4 PRE-EXAMINATION PROCESSES

5.4.1 General

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

5.4.2 Information for its Users

The information includes as appropriate (also Refer Sample Collection Manual):

a) The location of the laboratory;

b) Types of 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 patients;

g) Instructions for clinical samples;

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

i) Any requirements for patients '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 its users that includes an explanation of the clinical procedure to be performed to enable informed consent.

5.4.3 Request Form Information

The format of the request and the mode of communication to the laboratory are determined in discussion with the users of laboratory services. The laboratory always willingly cooperates with users or their representatives in clarifying any requests from the users. The laboratory accepts verbal requests and documents on Sample requisition bill. Any change in the test requested are communicated telephonically and written on Sample requisition bill and approved by Lab Director/Pathologist/Quality Manager before implementation. Records of change request are kept with concerned Sample requisition bill.

The request form contains sufficient information to identify the patient and the authorized requester, as well as pertinent clinical data.

- The request form has following information:
- Unique identification.
- Demographics which include gender, date of birth;
- Type and volume of primary sample;
- Examinations requested;
- Clinical information relevant to the tests for interpretation purposes;
- Date and time of primary sample collection;
- Date and time of receipt of samples by the laboratory.

5.4.4 Primary sample collection and handling

5.4.4.1. General

Specific instructions for the proper collection and handling of primary samples are documented in Sample Collection Manual and implemented by laboratory and made available to those responsible for primary sample collection.

Whenever the user requests for any deviations and exclusions from/ additions to the documented collection procedure they are recorded and included in all documents containing examination results and are communicated to the appropriate personnel.

Consents are taken from all patients for testing for HIV pre- and post-test counselling before sample collection. All patients are provided with adequate privacy and comfort during reception and sampling.

5.4.4.2. Instructions for pre-collection activities

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

1. Completion of Sample requisition bill.;
2. Preparation (e.g. phlebotomists and patients);
3. Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;
4. Special timing of collection, where needed;
5. 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 which is the unique identification;

b) Verification that the patient meets pre-examination requirements if any [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 samples, with descriptions of the primary sample containers and any necessary additives;

d) Instructions for labelling of primary samples in a manner that provides an unequivocal link with the patient from whom they are collected;

e) Recording of the identity of the person collecting the primary sample and the collection date and time;

f) Instructions for proper storage conditions (if required) for collected samples till delivered to the laboratory;

g) Safe disposal of materials used in the collection as per Bio-waste guidelines.

5.4.5 Sample Transportation

Samples are transferred across different sections within the time frame. For samples which are collected on floors or outsourced to referral labs, instructions are documented in sample collection manual for post-collection activities which include packaging, labelling and transportation.

The laboratory has a documented procedure (Sample collection manual); 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.

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 through Patient ID number which is allotted after registration in LIS along with Bill no

which is the visit no. All samples are analysed as Bill numbers which are given at every visit which are traceable to unique Patient ID number.

b) Samples are accepted in the lab based on laboratory-developed and documented acceptance or rejection criteria and recorded in Rejection logbook.

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 indicates the nature of the problem facilitating the required caution, while interpreting the result. Where possible, the lab seeks clarification from the collection area before testing the compromised sample and documenting the same.

d) All samples received are registered in LIS along with details of date and time of receipt and the identity of the person receiving the sample. In case of manually written details in register they are registered later once LIS is functional.

e) The lab personnel receiving the samples ensure that they meet the acceptance criteria relevant for the requested examination(s).

f) Where relevant, the urgent samples, as informed by the collection area, are received, processed and reported on urgent basis.

Primary samples are used and stored as such. If and when they are made from primary sample, they will be labelled by same unique ID so they are unequivocally traceable to the original primary sample.

5.4.7 Pre-examination handling, preparation and storage

All primary samples are stored as per NABL 112 guidelines in their original vacutainers under conditions ensuring stability of sample properties. The samples are stored to enable repetition of the examination after reporting of the result or for additional examinations requested during retention period.

Related Procedures/Manuals/Forms

- **SH/MAN/02**

5.5 EXAMINATION PROCESSES

5.5.1 Selection, Verification and Validation of Examination Procedures

5.5.1.1 General

The laboratory uses only validated examination procedures which are intended for use and are published in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines, or national or regional regulations. The specified requirements (performance specifications) for each examination procedure also relate to the intended use of that examination. The identity of persons performing activities in examination processes are recorded in LIS.

5.5.1.2 Verification of Examination Procedures

All the examination procedures used in the lab are validated and are used without any modifications. The laboratory conducts independent verification of the performance claims of the manufacturer for the examination procedure. The performance claims for the examination procedure confirmed during the verification process are those relevant to the intended use of the examination results. Verification report for the new method/equipment is prepared by the Quality Manager and reviewed by Lab Director/ Pathologist /Designee before being introduced in the laboratory.

5.5.1.3 Validation of Examination Procedures

The laboratory uses only unmodified validated methods but will validate examination procedures if the methods are:

a) Non-standard methods;

b) Laboratory designed or developed methods;

c) Standard methods used outside their intended scope;

d) Validated methods subsequently modified.

In such cases, the validation will be 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 will 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 will develop and document the procedure used for the validation and record the results obtained. The designated authority will review the validation results and record the review. Whenever changes are made to a validated examination procedure, the influence of such changes will also be documented and, when appropriate, a new validation will be carried out.

5.5.1.4 Measurement Uncertainty of Measured Quantity Values

The laboratory has defined the performance requirements for the measurement uncertainty of each measurement procedure in method verification SOP and reviews estimates of measurement uncertainty every month. The laboratory determines measurement uncertainty in terms of %CV for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. It is calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions which include as many routine changes as reasonably possible in the standard operation of a measurement procedure, e.g. changes of reagent, control and calibrator batches, different operators, scheduled instrument maintenance.

NOTE 1: The relevant uncertainty components are those associated with sampling, sample processing, reagents, reference material, equipment and environmental condition, the actual measurement process, commencing with the presentation of the sample to the

measurement procedure and ending with the output of the measured value. The laboratory always considers % CV when interpreting measured quantity values. Upon request, the laboratory provides its estimates of measurement uncertainty to its users.

Currently no such examinations are done which include a measurement step but do not report a measured quantity value. However, if required, then the laboratory will calculate the uncertainty of the measurement step wherever it has utility in assessing the reliability of the examination procedure or has influence on the reported result.

5.5.2 Biological Reference Intervals (BRI) or Clinical Decision Values

The laboratory has defined the biological reference intervals from standard reference textbooks / reagent kit inserts and approved by consensus between clinicians and lab staff, before being used. Thereafter the lab reviews the BRI with clinicians every year for its appropriateness for the population served. The verified biological reference intervals or any changes made are also communicated to the users of lab services. When the laboratory changes an examination procedure or pre-examination procedure, the laboratory will verify/review the associated reference intervals and clinical decision values, as applicable and records will be maintained.

5.5.3 Documentation of Examination Procedures

All examination procedures are documented as SOPs/WIs. They are written in a language commonly understood by the staff in the laboratory and are available in relevant locations. Any condensed document format (e.g. summarised table, flow charts or similarly used systems) corresponds to the documented procedure.

NOTE 1 Working instructions, flow charts or similar systems 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.

NOTE 2 Information from product instructions for use are also 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 participant 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 (see 5.5.1.2 and 5.5.1.3);
d) type of sample (e.g. plasma, serum, urine);
e) patient preparation is included in sample collection manual;
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, bilirubinemia, 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 available in report SOP;
o) reportable interval of examination results;
p) instructions for determining quantitative results when a result is not within the measurement interval such as dilution protocol;
q) alert/critical values, where appropriate available in report SOP;
r) laboratory clinical interpretation;
s) potential sources of variation if any;
t) references.

When the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications are explained to users of the laboratory services after validating/verifying the procedure. Records of mail/minutes of the meeting to communicate the changes and implication to users are maintained in the laboratory.

Related Procedures/Manuals/Forms

- **All SOPs**

5.6 ENSURING QUALITY OF EXAMINATION RESULTS

5.6.1 General

Laboratory is committed to quality through well laid down Quality System Procedures, Standard operating procedures, validated methods using calibrated instruments, Standard reagents and kits, qualified and trained manpower, quality techniques and good laboratory practices. The laboratory ensures that the results are not fabricated at any point of time. The laboratory has a well-defined procedure for conducting internal and external quality control program.

5.6.2 Quality Control

5.6.2.1 General

The laboratory uses quality control materials for each assay it performs as mentioned in individual assay SOPs and internal and external quality control program QSP to verify the attainment of the intended quality of results. All the concerned personnel are well trained on the quality control measures of the test results.

5.6.2.2 Quality Control Materials

The laboratory ensures that the quality control materials used in the lab react to the examining system in a manner as close as possible to clinical samples. The frequency of examination of quality control materials is defined in the QSP and is based on the stability of the procedure and the risk of harm to the patient from an erroneous result. The laboratory ensures control materials used are, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made. The laboratory also ensures that independent third-party control materials, where ever possible are considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

Note: Third party controls are either that which is not prepared from the same master lot from which the calibrator is derived or provided by different manufacturer but it should be suitable for the method used.

5.6.2.3 Quality Control Data

The laboratory procedure defines that samples will not be tested unless and until the IQC results are satisfactory for the analyser used. The lab performs root cause analysis and takes corrective actions as and when out of control situations are detected as defined by the QSP. The laboratory reviews daily the quality control data to detect systematic (trends or shifts) and random errors. When any such trends are noted, preventive actions are taken and recorded. The daily QC values are entered in Quality Control part of LIS (Live Health) which calculates %CV from the monthly QC data and gives LJ Charts. The laboratory maintains control charts to demonstrate stability of the analytical measuring systems.

5.6.3 Interlaboratory Comparisons

5.6.3.1 Participation

The laboratory procedure defines the responsibilities, instructions and frequency of participation in interlaboratory comparison programme(s) such as an external quality assessment programme/ proficiency testing programme for Clinical Biochemistry Haematology and Clinical Pathology, Serology.

which are appropriate to the examination and interpretations of examination results. The laboratory procedure also defines the evaluation criteria and review of results of the interlaboratory comparison programme(s) and implementation of corrective actions when predetermined performance criteria are not fulfilled.

5.6.3.2 Alternative Approaches

Whenever EQAS/PT program is not available, the laboratory exchanges samples (ILC) with one other identified NABL accredited laboratory to provide objective evidence for determining the acceptability of examination results. Whenever possible, this mechanism may also utilize other appropriate materials such as --certified reference materials, samples previously examined; or control materials that are tested daily in interlaboratory comparison programmes.

5.6.3.3 Analysis of Interlaboratory Comparison Samples

EQAS/PT/ILC samples are integrated within the routine laboratory workload, and analyzed by personnel who routinely test samples, using primary method systems. If and when EQAS/PT/ILC samples are available, the backup personnel also analyse the samples and evaluation is done in house as a part of competency evaluation of the individual. The laboratory does not communicate with other participants in the interlaboratory comparison programme about sample data nor does it refer interlaboratory comparison samples for confirmatory examinations before submission of the data.

5.6.3.4 Evaluation of laboratory performance

The performance in interlaboratory comparisons are reviewed on receipt of results and discussed with relevant lab personal. When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff participate in the implementation and recording of appropriate corrective actions based on the EQA evaluation report as also defined in QSP. The effectiveness of corrective action is monitored during quality indicator monitoring. The EQAS/ILC results are also evaluated for trends which indicate potential nonconformities and accordingly preventive actions are taken.

5.6.4 Comparability of Examination Results

When the laboratory uses more than one measuring system where the measurements are not traceable to the same reference material / reference method, or the biological reference interval are different, it performs a comparability study between the two systems and prove that there is agreement in performance throughout appropriate clinical intervals at least twice in a year using Bland - Altman plot and / or regression analysis. The laboratory documents, records and as appropriate, expeditiously act upon results from these comparisons. Problems and deficiencies identified are acted upon and records of action taken retained.

Related Procedures/Manuals/Forms

- **SH/QSP/09**

5.7 POST-EXAMINATION PROCESSES

5.7.1 Review of results

The laboratory has a documented procedure to ensure that the results are systematically reviewed against internal quality control and, as appropriate, available clinical information and previous examination results before they are approved for release. Procedures also ensure that only authorized personnel release the results. Automated selection and reporting is not practised in the laboratory.

5.7.2 Storage, Retention and Disposal of Clinical Samples

The laboratory has well defined procedures (Sample Collection Manual) for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. The laboratory retains samples in accordance with NABL 112 for retesting/ additional tests, which is defined by the nature of the sample, the examination and other applicable requirements.

Safe disposal of samples is carried out as per the documented procedure which is in accordance with local regulations/recommendations for waste management.

Related Procedures/Manuals/Forms

- **SH/QSP/10**

5.8 REPORTING OF RESULTS

5.8.1 General

The results of each examination are reported accurately, clearly, unambiguously and in accordance with any specific instructions if required in the examination procedures through Lab Information System/ back up manual method. After discussion with the Lab service users/lab management, the lab has defined the report format, medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated to the user. The laboratory has procedures to ensure the correctness of transcription of laboratory results which is verified by the analyst before approval by authorised signatory. Report format also ensures provision to include the information necessary for the interpretation of the examination results such as compromised quality, quantity not sufficient, recommendations, etc. The laboratory ensures the requester is notified when an examination is delayed which could compromise further 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 in Remark section if required;

b) comments regarding sample suitability with respect to rejection criteria in Remark section if required;

c) critical results in Remark section, where applicable;

d) interpretive comments on results in Remark section, where applicable.

5.8.3 Report Content

The report format includes, but not 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 (sometimes referral lab reports are sent in their original format);
d) Patient identification on each page of the report;
e) the requester's unique identification;
f) date of primary sample collection (and time, when available and relevant to 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;
k) interpretation of results, where appropriate;
l) remark section for comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, details of critical values notified, details of amended report if any , use of developmental procedure if any) if required;
m) Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;
a) identification of the person(s) reviewing the results and authorizing the release of the report;
b) date of the report, and time of release;

c) page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.) for individual reports from different sections.

Related Procedures/Manuals/Forms

- **SH/QSP/10**
- **SH/MAN/02**

5.9 RELEASE OF RESULTS

5.9.1 General

The laboratory has well established documented procedure for the release of examination results which include 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, it is indicated in the remark section of the report.

b) Laboratory in consultation with the Clinicians, has established “alert” or “critical” intervals. When examination results fall within established “alert” or “critical” intervals: All critical values are confirmed by retesting but first value is reported. Clinician/designee is notified immediately, which includes results received on samples sent to referral laboratories for examination, by telephone followed by e-mail. Verbal (telephonic) communication is recalled ensuring correct communication of critical value. The details of communication are documented in the remark section of report. Email copies of communications are maintained that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and difficulties encountered in notifications, if any.

c) All analysers are interfaced with the LIS minimizing the transcriptional errors. Final Check (completed by) is done by date entry operators to verify the correct transmission/transcription and reporting of results before final approval by authorised signatory. In case of manual entry of results, 100% QC is done by concerned Lab Personal before final approval by authorised signatory. Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.

d) The lab may provide interim reports telephonically and document in telephonic reporting record. The lab ensures all interim reports are followed by final authorised reports.

e) The laboratory results, if requested, and critical values are informed telephonically and documented in Telephonic reporting record. Clinical Lab report procedure ensure that

such results distributed by telephone/ electronic means are correctly heard through read back policy and reach only authorized recipients. All results provided verbally are followed by a written report and records of details are maintained.

5.9.2 Automated selection and reporting of results

Automated selection and reporting is not practised by the laboratory.

5.9.3 Revised Reports

Amendments of reports are done on email request which is approved by the Lab Director/Pathologist/Quality Manager. Report QSP defines process for amendment of reports so as to ensure:

a) the revised report is clearly identified as “amended report” with details of date and identification of the participant.

b) the user is made aware of the revision by including the details of revision in the remark section of the report;

c) the revised report shows the time and date of the change and the name of the person responsible for the change;

d) the wrong entry on the original report is replaced in LIS by the revised correct entry and captured in LIS in audit trail. Copies of both original as well as amended reports are kept in lab. Records of email requesting amendment of report which is approved by the Lab Director/Pathologist/ Quality Manager is also kept in separate file.

Related Procedures/Manuals/Forms

- **SH/QSP/10**

5.10 LABORATORY INFORMATION MANAGEMENT

5.10.1 General

The laboratory has well defined documented procedure for use of Lab Information system (Live Health Care) for registration, data transmission through interfacing and reporting of results as per the needs and requirements of the user. Lab Information system (Live Health Care) is also used for purchase, receipt and inventory management of reagent and consumables. All computers and Softwares used in lab have password protected user account and restricted access to ensure confidentiality of patient information and other lab data and to prevent unauthorised access.

5.10.2 Authorities and Responsibilities

The laboratory procedure ensures that the authorities and responsibilities for the management of the information system are defined in SOP, which includes the maintenance/modification to and backup of the lab information system(s) that may affect patient care.

The laboratory procedure also defines the authorities and responsibilities of all personnel who use the system, in particular 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 Lab information system used for the collection, processing, recording, data transmission, reporting, storage or retrieval of examination data and information is:

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; All reports are QA checked to verify the correct transmission/transcription and reporting of results.

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 by providing password protected user accounts and audit trail;

d) Safeguarded against tampering or loss;

e) Operated in a clean and controlled 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; all computerized systems are connected to uninterruptible power supply (UPS).

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 in maintenance logbook; "Downtime" for maintenance is managed by IT department of Lab and is scheduled and pre- informed to minimize interruption of lab services.

g) In compliance with national or international requirements regarding data protection.

The laboratory also verifies that data transmission and the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant. When a new examination is implemented, the laboratory re verifies the functioning of the software. The laboratory also has a backup manual system (Register) to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service. LIS is web based. It is the responsibility of the laboratory personnel to ensure that the provider/operator of the system complies with all applicable requirements of this International Standard.

Related Procedures/Manuals/Forms

- **LIS Manual provided by Mednet**