SRI LANKA ACCREDITATION BOARD for
CONFORMITY ASSESSMENT

SPECIFIC CRITERIA FOR

MEDICAL/CLINICAL TESTING LABORATORIES

CONTENTS

1. INTRODUCTION

1.1 The Accreditation Scheme for Medical/Clinical Laboratories of the Sri Lanka Accreditation Board (SLAB) is based on the requirements laid down in ISO 15189:2022 *Particular requirements for quality and competence*. Medical/Clinical Laboratory Testing Services cover a wide range tests in different fields of testing. Specific fields under Medical/Clinical testing for which SLAB offers accreditation based on ISO 15189 is given in Section 2 of this document.

1.2 The requirements stipulated in ISO 15189 apply to Medical Testing Laboratories providing all types of testing in different fields. However, in certain instances additional guidance is considered necessary to take into account the type of testing, techniques involved and the expertise required for different tests.

1.3 This specific criteria document has been prepared by the Technical Advisory Committee on Medical Testing and has been authorized for adoption by the Council of the Sri Lanka Accreditation Board (SLAB). Medical/Clinical Laboratories seeking accreditation are required to comply with all the requirements listed in the international standard ISO 15189. This document supplements International Standard ISO 15189 and provides guidance for the accreditation of Medical/Clinical testing laboratories for both assessors and for laboratories preparing for accreditation.

1.4 This Specific Criteria document must be used in conjunction with ISO 15189. It provides an interpretation of the latter document and describes specific requirements for those clauses of ISO 15189 which are general in nature. Corresponding reference to the Clauses in ISO 15189 is indicated in parenthesis in the text of the document. This document should be read in conjunction with the Rules and Procedures of SLAB as applicable to Medical Laboratories. Further, all Medical Laboratories shall comply with any national, regional and local laws and regulations as applicable.

1.5 The field of Medical/Clinical Testing involves a wide variety of test methods and techniques requiring different levels of knowledge and expertise in the performance of tests and interpretation of results. To provide for a higher level of consistency in the interpretation of requirements of this Standard in the assessment process and to facilitate the accreditation procedure, the tests performed in Medical/Clinical Laboratories have been classified as Routine, Special and Highly Specialized tests under each field of testing as given in Appendix A.

1.6 This document will be periodically reviewed and updated based on experience gained and developments in technology.

2. SCOPE OF ACCREDITATION

The scope of the accreditation is applicable to the following medical laboratory services: (2.1 to 2.12)

2.1 **Clinical Pathology:** Service includes the examination of basic blood and urine samples.

2.2 **Clinical Biochemistry:** Service includes the examination of blood, urine and other body fluids for biochemical investigation.

2.3 **Chemical Pathology:** Service includes Clinical Biochemistry and examinations such as Clinical Endocrinology, Hormone assays and Biochemical Tumor markers.

2.4 **Haematology and Immunohaematology:** Service includes the examination and analysis of blood and bone marrow for haematological investigations including Immunophenotyping and Cytogenetics.

2.5 **Microbiology and Serology:** Service includes Bacteriology, Virology, Mycology, Parasitology and microbial specific serological tests on clinical samples.

2.6 **Histopathology/Cytopathology:** Service includes histopathology, cytopathology, histochemistry, immunofluorescence, Immunohistochemistry and Molecular morphology .

Note: Histopathology services include examination and analytical interpretation of human tissues. Cytopathology services include examination and analytical interpretation of cytological specimens

2.7 **Immunology:** Service includes the investigation of immuno deficiency and allergy.

2.8 **Molecular Biology:** Molecular biological techniques used in the diagnosis of infectious, genetic and other disorders.

2.9 **Pharmacology:** Service includes Theraputic Drug Monitoring, Toxicological Investigations and Drugs of Abuse.

2.10 **Nuclear Medicine:** Immunological Techniques for hormone assays and Tumor markers detected by radioisotopes.

2.11 **Andrology:** Service includes Seminal Fluid Analysis (SFA), Sperm processing for Intra Uterine Insemination (IUI) and Sperm Freezing.

2.12 **Embryology:** Service includes Invitro Fertilization Techniques and Embryo Freezing.

***Note*:** Immunological techniques are common to many disciplines. Therefore, the immunological tests can be listed under respective disciplines.

The accreditation shall be considered only for those tests, which the laboratory is in itself equipped and competent to carryout. The facility for primary sample collection at sites other

than its main laboratory shall also comply with the relevant requirements of ISO 15189: 2022. A representative sample of these facilities shall be assessed by SLAB for their compliance with the requirements.

3. DESCRIPTION AND TYPE OF LABORATORY

The requirements given in this document are applicable to all medical laboratories applying for SLAB accreditation regardless of the level at which they function (small/ medium/ large) or the place in which they are located (district / city / town) or whether they are private/ government/ semi government attached to a hospital or stand-alone.

The tests are stratified according to the requirements that apply in various laboratory situations, according to the technical complexity in the testing process and risk of harm in reporting erroneous results. Three categories of testing are established on the basis of the complexity of the testing methodology. Laboratories may perform tests in only one category of testing or in any combination of the three.

Basic (Routine) Tests: Test with direct application of principles which can be performed by simply following the procedural steps given in the method (manufacturer instructions) and with low chances of negative outcomes if performed inaccurately. Results can be released by an SLMC registered MLT.

Special Tests: More complex than Basic Tests and need to be performed under specific conditions, with high degree of control and accuracies (Tests of moderate complexity*). High degree of competency and skills required for the person performing tests. Special tests require clinical validation.

Highly Specialized Tests (Tests of High Complexity*): Usually non- automated or complicated tests requiring considerable clinical judgment. High level of competency with through knowledge of the theoretical background is required for the person performing tests. Results should only be issued with clinical validation of the consultant specialist.

* Moderate or high complexity is identified according to seven criteria: a) degree of knowledge needed to perform the test; b) training and experience required; c) complexity of reagent and materials preparation; d) characteristics of operational steps; e) characteristics and availability of calibration, quality control, and proficiency testing materials; f) troubleshooting required; and g) degree of interpretation and judgment required in the testing process.

4. GENERAL REQUIREMENTS

4.1 Impartiality

Laboratory activities shall be undertaken impartially and structured so as to safeguard impartiality: the organizational structure shall be such that there is no conflict of interest with other activities, defining the responsibilities: this may be seen where organization defines the structure particularly where the laboratories are the part of larger organization.

For being impartial, laboratory shall conduct its activities without any bias. Results of the laboratory should not be compromised due to being influenced by any relationships of the laboratory's personnel involved in the activities of the laboratory, with its customer.

To safeguard the impartiality in an organization shall clearly define the segregation of the activities in its organization which may be vulnerable to threat/risks to impartiality.

Threat/risks to impartiality may also arise within the laboratory itself by means of creating undue pressure on the analysts/ technicians to skip the test procedural steps for faster results delivery or to overlook the adverse results which will distress a Patient. Further undue pressure may also include offering monetary incentives to the employees for the number of tests conducted or the results of test. It is suggested that the identification of risks to impartiality should be carried out on an on-going basis or at a regular interval.

4.2 Confidentiality

Legally enforceable commitments may be in the form of contract / agreement / work order between the laboratory and its patient.

5. STRUCTURAL AND GOVERNANCE REQUIREMENT

5.1 Legal Entity (Cl. 5.1 of ISO 15189:2022)

It is the responsibility of the laboratory to carry out its work in accordance with the relevant Laws and Regulations of Sri Lanka.

Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as operation, commercial marketing or financial should not adversely influence the laboratory's compliance with the requirements of this document. The laboratory management shall have evidence in place to demonstrate its arrangement to ensure staff do not work under undue pressure that may affect the integrity and quality of their work.

A laboratory operating at more than one location having the same legal identity will be accredited separately; the application for accreditation should be submitted separately for each location. The laboratory operating at more than one location having separate legal identities will be treated as independent laboratories even though they are part of same the organization.

5.2 Laboratory Director (Cl. 5.2 of ISO 15189:2022)

The Laboratory Director, and divisional heads of each discipline in the case of large laboratories, shall have broad knowledge of medical and clinical laboratory sciences, and laboratory operation. They shall provide adequate supervision and have the ability to make critical evaluations of examination results.

He/ She shall have the overall responsibility of Technical / Advisory / Scientific operations of the laboratory. Laboratory Director shall be a full-time employee of the laboratory[#]. He/ She shall be responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed. Duties and Responsibilities of the laboratory director shall be documented. He/ She may delegate selected responsibilities to qualified and competent personnel and such delegation shall be documented. The Laboratory Director/designee shall also fulfill the other requirements of ISO 15189:2022.

#In a Mini/Micro/Small laboratory, the Laboratory Director can be a part time* employee. Other requirements/responsibilities remain the same.

*part time - minimum of four hours per day.

In a hospital setting or in a large or very large laboratory, each department/discipline may have a separate head. However, one of them if delegated as Laboratory Director, will be available for consultation and responsible for overall operations.

5.3 Laboratory Activities

Advisory activities

Irrespective of the type of laboratory, i.e., Stand-alone or hospital-based, the laboratory shall have arrangements to communicate with its users for fulfilment of the requirements of the standard with regard to the choice of examinations and interpretations. Communication may be through direct contact, email etc. Hospital-attached laboratory personnel are encouraged to participate in clinical rounds and meetings.

5.4 Structure and authority

Quality Management

Laboratory shall have personnel for implementation, maintenance and improvement of management system for e.g., Quality officer/Quality Manager (how so ever named), either with dedicated or with other responsibilities.
He/ She shall be a full-time employee.

5.5 Objectives and Policies

Laboratory management shall establish and maintain objectives and policies (see 8.2 of ISO 15189:2022) to:

1) meet the needs and requirements of its patients and users;
2) commit to good professional practice;
3) provide examinations that fulfil their intended use;
4) conform to this document.

Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organization.

5.6 Risk management

i. The components of risk management are:

- Risk identification - identification and listing of all risks across the entire testing processes covering pre-examination, examination, post-examination, manpower, equipment, facility and design, supplies, Quality control practices, policies etc.
- Risk evaluation based on severity and likelihood of occurrence and detectability of occurrences, prioritization of risks.
- Risk mitigation through preventive actions.
- Estimation of residual risk, through monitoring.

ii. The laboratory shall review its risk management at least once a year and whenever there is a change in process or design; records shall be kept that reflect the identified risks, their priority, actions taken to eliminate them and their effectiveness.

6. TECHNICAL & MANAGEMENT SYSTEM REQUIREMENTS FOR ALL DISCIPLINES (6 to 8 of ISO 15189:2022)

6.1 Personnel (6.2 of ISO 15189:2022)

The laboratory shall document its procedure for personnel management including the recruitment, training, leave, promotion, health, safety and immunization of laboratory staff.

The appraisal of personnel is a major part of each laboratory assessment as the standard of performance depends largely on the skills of the laboratory's personnel. The continuing training programmes shall be defined and annual refreshing training courses should be provided to staff. Staff are expected to be assessed at least annually for their competence in performing assigned managerial or technical tasks.

Safety training shall be included as part of the training programme and documented. Competence shall be demonstrated by evidence of continuing practice and experience in the specialty, with documented participation in appropriate continuing professional development (CPD). CPD could be in the form of attending accredited courses, conferences and seminars, journal based learning, refereed publications, giving lectures, seminars, conference presentations, etc.

Four categories of personnel will be assessed. They are:-

a) Professional personnel responsible for providing clinical interpretations
b) Management personnel, including the Laboratory Director
c) Supervisory personnel
d) Technical personnel

Laboratory management shall ensure that any special requirements of legislation and regulations on personnel shall be met. Competency assessment of staff is normally conducted by respective supervisors. Evidence of satisfactory performance in External Quality Assurance programmes and records of continuing medical education (CME) or continuing professional development (CPD) shall be considered as objective evidence of continuing competence and effort made to keep abreast with technology advancement.

Colour vision defects may prevent some people from performing some work satisfactorily (such as in anatomical examination, and chemical or microbiological testing). It is the responsibility of the laboratory management to ensure in such cases, colour vision problems will not affect validity of results.

Persons authorized to review and release the results shall demonstrate knowledge and competence in the relevant field of work.

Medical/Clinical Testing and Examination procedures involves a wide variety of techniques and test procedures requiring different levels of knowledge, expertise and experience in the

performance of test and interpretation of results. The tests performed in medical laboratories have been classified as Routine, Special and Highly specialized tests based on complexity and the nature of tests.

The Laboratory should be able to ensure the competence of each technical staff member in performing applicable task with documentary evidence. Qualification and experience requirements for various laboratory personnel have been listed in relation to the test classification.

6.1.1 Qualification norms for Persons authorized to review and release the results are listed below.

(Refer Appendix A for a listing of Highly Specialized, Special and Routine tests under each field of testing)

The final signatory authority for tests requiring clinical validation shall be a Consultant with an M.D. in the relevant discipline. In the absence of such expertise, the laboratory shall limit its scope to exclude clinical validation and perform only routine testing. A suitably qualified Consultant shall oversee both routine and specialized testing.

Chemical Pathology / Clinical Biochemistry / Clinical Pathology*

Test Classification	Qualifications	Experience	Other requirements/Remarks **
Highly Specialized Tests	M.B.B.S with M.D. (Chemical Pathology) *or* Equivalent Qualifications	1 year's post qualification experience	Demonstrate knowledge and competence in Clinical Biochemistry, Clinical Endocrinology and Biochemical Tumor Markers.
Special Tests	As above *or* MBBS with Diploma in Pathology or Chemical pathology	1 year post qualification experience in the relevant field	
	or BSc in Chemistry with MSc in Clinical Chemistry or Analytical Chemistry	2 years' experience in a Chemical Pathology Laboratory	(Note 1 & 2)
	or BSc & MSc degree in Clinical Laboratory Sciences (with Biochemistry as a subject)	2 years' experience in a Chemical Pathology Laboratory	(Note 1 & 2)
	Or SLMC registered MLTTs	1 year experience in a Chemical Pathology Laboratory	Technical Validation & Release of reports (Note 1 & 2)

Routine Tests	As above *or* M.B.B.S *or* BSc in Chemistry with MSc in Clinical Chemistry or Analytical Chemistry *or* BSc / MSc degree in Clinical Laboratory Sciences (with Biochemistry as a subject) *or* BSc *or* Diploma/Certificate in Medical Laboratory Technology or equivalent training	1 year experience in Laboratory Medicine 1 year experience in a Chemical Pathology laboratory 1 year experience in a Chemical Pathology Laboratory 3 years experience in a Chemical Pathology Laboratory 6 month experience in a laboratory (if there is a discontinuation for more than 2 years) (Note 1)	(Note 1 & 2) (Note 1 & 2) (Note 1 & 2) (Note 1 & 2) Release of results (Technical Validation).

******All categories should be SLMC registered professionals currently practicing in the relevant field*

Note 1: *Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in the relevant medical discipline. Release of results should be supervised by the higher category where relevant.*

Note 2: *The evaluation of authorized signatories shall be carried out by a consultant. The evaluation process shall be comprehensive, continuous, and task-based, and shall be conducted at least annually. Prior to the assignment of any task, the laboratory shall perform an initial evaluation of the authorized signatory.*

Haematology and Immunohaematology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	M.B.B.S with M.D. (Haematology) *or* Equivalent Qualification	As appropriate for the test	Demonstrate knowledge and high competence Clinical & Technical Experience (Note 1 & 2)
Special Tests	As above *or* MBBS with Diploma in Pathology *or* BSc / MSc degree in Clinical Laboratory Sciences	06 months post qualification experience in the relevant field (Note 1) 06 months post qualification experience in the relevant field (Note 1)	(Note 1 & 2) (Note 1 & 2)

Routine Tests	As above *or* M.B.B.S *or* BSc / MSc degree in Clinical Laboratory Sciences *or* Diploma/Certificate in Medical Laboratory Technology or equivalent training	Six (06) months experience in Laboratory Medicine (Note 1) 03 months experience in a laboratory (Note 1) One year experience in a laboratory (Note 1)	(Note 1 & 2) (Note 1 & 2) Release of results under the supervision of a Pathologist/Head of the Laboratory or designee. MLTs registered with the Sri Lanka Medical Council are exempted from supervision requirement. (Note 1 & 2)

Note 1: *If the Degree/Diploma or Certificate programme includes adequate Laboratory Practice, experience component may be reduced*

Note 2: *Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in the relevant medical discipline.*

Microbiology and Serology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	M.B.B.S with a) M.D. (Medical Microbiology, Virology, Parasitology or Mycology as relevant) and Board certification *or* b) Equivalent Specialist Qualification recognized by the SLMC*	As appropriate for the test	Highly specialized tests should be performed in a laboratory where a relevant Consultant has the overall responsibility. Person who performs the test is responsible for technical validation. Results of highly specialized tests should be released only with clinical validation, which should be done by a relevant Consultant.
Special Tests	M.B.B.S with a) M.D. (Medical Microbiology, Virology, Parasitology or Mycology as relevant) and Board certification *or* b) Equivalent Specialist Qualification recognized by the SLMC* *or* c) Diploma in Medical/ Clinical Microbiology *or* d) B.Sc. / MSc in Medical/Clinical Microbiology	As appropriate for the test 06 months post qualification	Person who performs the test is responsible for technical validation Doctors with Diploma or MSc in Medical/Clinical Microbiology and 06 months post qualification experience can release the results with clinical validation under supervision of the respective Consultant.

**As per the Specialist register maintained by the Sri Lanka Medical Council*

Test Classification	Qualifications	Experience	Other requirements/Remarks
Routine Tests	(1) M.B.B.S with a) M.D. (Medical Microbiology, Virology, Parasitology or Mycology as relevant) and Board certification *or* b) Equivalent Specialist Qualification recognized by the SLMC* *or* c) Diploma in Medical/ Clinical Microbiology / Pathology *or* d) MSc in Medical/Clinical Microbiology	As appropriate for the test	
	or (2) M.B.B. S	03 months in a laboratory	
	o*r* *(3)* BSc in MLS with SLMC registration + Post graduate qualification in relevant filed *or* BSc in MLS with SLMC registration *or* Diploma MLT with SLMC registration	As appropriate for the test	

**As per the Specialist register maintained by the Sri Lanka Medical Council*

Note 1: *If the Degree/Diploma or Certificate programme includes adequate Laboratory Practice, experience component may be reduced*

Note 2: *Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in the relevant medical discipline.*

Histopathology/ Cytopathology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	M.B.B.S and M.D. (Histopathology) with board certification granted by the Postgraduate Institute of Medicine, University of Colombo, Sri Lanka	As appropriate for the test	Demonstrate knowledge and competence and continual professional development
Special Tests	As above	As above	As above
Routine Tests	As above	As above	As above

Note: *Providing Opinions and Clinical interpretations of test results should be done by personnel having above qualifications.*

Immunology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	M.B.B.S and M.D. in Chemical Pathology / Haematology with experience in Clinical/Laboratory immunology	2 years	Demonstrate knowledge and high competence Clinical and Technical Experience.
	Microbiology and Serology M.B.B.S with a) M.D. (Medical Microbiology, Virology, Parasitology or Mycology as relevant) and Board certification *or* b) Equivalent Specialist Qualification recognized by the SLMC*		Highly specialized tests should be performed in a laboratory where an appropriately qualified Specialist has the overall responsibility. Person who performs the test is responsible for technical validation. Results of highly specialized tests should be released only with clinical validation. Clinical validation should be done by a suitably qualified Specialist.
Special Tests	Not relevant for Microbiology and Serology		
Routine Tests	Not relevant for Microbiology and Serology		

**As per the Specialist register maintained by the Sri Lanka Medical Council*

Note 1: *If the Degree/Diploma or Certificate programme includes adequate Laboratory Practice, experience component may be reduced*

Note 2: *Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in the relevant medical discipline.*

Molecular Biology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	Post graduate degree in Molecular Biology (PhD/MPhil/MSc) M.B.B.S/M.D. in Chemical Pathology/Haematology/Microbiology/ Histopathology with experience in Molecular Biology *or* BSc / MSc degree in Clinical Laboratory Sciences	2 years 2 years	Demonstrate knowledge and high competence in Molecular Biological Diagnostic Techniques Clinical and Technical Experience

Note 1: *If the Degree/Diploma or Certificate programme includes adequate Laboratory Practice, experience component may be reduced*

Note 2: *Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in the relevant medical discipline.*

Pharmacology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	PhD in Pharmacology with experience in Clinical Pharmacology or MBBS/MD in Chemical Pathology/ Clinical Pharmacology with experience in Clinical Pharmacology	2 years	Demonstrate knowledge and high competence in Clinical Pharmacology Clinical and Technical Experience

Note 1: *If the Degree/Diploma or Certificate programme includes adequate Laboratory Practice, experience component may be reduced*

Note 2: *Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in the relevant medical discipline.*

Nuclear Medicine

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	PhD in Nuclear Medicine or M.B.B.S. /M.D in Chemical Pathology	2 years	Demonstrate knowledge and high competence Clinical and Technical Experience

Note 1: *If the Degree/Diploma or Certificate programme includes adequate Laboratory Practice, experience component may be reduced*

Note 2: *Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in the relevant medical discipline.*

6.1.2 Qualification norms for Laboratory Staff assigned to perform tests, Operate test equipment and Laboratory support functions

Test Classification	Qualifications (minimum)	Experience	Remarks
Highly Specialized Tests	SLMC registered Diploma Certificate in Medical Laboratory Technology / BSc in Medical Laboratory Science and / or a specifically related discipline or Qualifications required as decided by the Management and Consultant, based on the nature and complexity of tests	Not applicable	The test performance may be decided by the management and by the persons having qualifications as specified in 5.1.2
Performance of Special Tests	SLMC registered Diploma Certificate in Medical Laboratory Technology / BSc in Medical Laboratory Science and / or related discipline Or A/L 03 subjects with Chemistry and/or Biology as one subject	06 months Two years	In relevant discipline
Performance of Routine Tests	SLMC registered Diploma Certificate in Medical Laboratory Technology / BSc in Medical Laboratory Science and / or related discipline or A/L 03 subjects with Chemistry and /or Biology as one subject	06 months One year training	In relevant laboratory discipline
Nurses	O/L/ with adequate training	One year	
Support Staff	Minimum Grade 8	Six months	A minimum period of one month of focussed training in the relevant laboratory discipline.

Note: *If persons with lower educational qualifications are assigned to perform routine tests, the management /Consultant shall ensure that adequate training ,evaluation and supervision is provided in the performance of test.*

62 Facilities and environmental conditions (6.3 of ISO 15189:2022)

Facilities and environmental condition requirements vary greatly depending on the nature of the samples to be examined or tested and the order of accuracy required of the examinations or tests. The laboratory and its personnel shall follow local and international biosafety requirements. Suitability of the accommodation and environmental conditions for a specific range of examinations and tests will be judged against how they affect :

(a) the integrity of the samples tested or examined;
(b) the performance of laboratory equipment;
(c) the competent performance of laboratory staff;
(d) compliance with the conditions set in test or examination methods;
(e) safety of laboratory staff.

Consideration of environmental effects on samples to be examined includes precautions necessary to prevent contamination and degradation. The areas for the sample preparation, preconditioning, testing or examination and storage shall be of adequate size, free from dust and fumes and protected from other environmental factors such as excessive temperature, high humidity and direct sunlight, which may affect the integrity of the samples. If samples require refrigeration before and after examinations, refrigerators or freezers of adequate capacity shall be provided.

Sufficient storage space shall be available to retain samples for the required periods in conditions designed to maintain their integrity.

Factors of the environment that may affect the performance of equipment include corrosion, temperature, humidity, vibration, electrical power stability, dust and electromagnetic influences. The location of all items of equipment likely to be affected by these factors shall be chosen to eliminate or minimize any adverse effects.

Accommodation and environmental conditions may also be judged on how it affects staff competence in performing specific tests. There shall be sufficient space available for staff to perform their duties comfortably, with adequate provision of lighting and with precautions taken to minimize noise.

Adequate space shall also be provided for laboratory clerical functions (recording, reporting and documentation activities) and for separate amenity facilities. All necessary services for gas, water, power (suitably stabilized if necessary), waste disposal and for extraction of fumes shall be available and be conveniently located.

Some examination methods also specify features of the environment in which sample preparation, and examination should take place. Where environmental features such as temperature and humidity ranges, airflow rates, illumination levels, etc., are specified, these conditions must be met in the relevant testing, examination and sample preparation sections of the laboratory.

6.2.1 Haematology:

Specimen Collection area – This could be a separate room or area with adequate lighting.
Procedure room - for Bone Marrow Biopsying: with adequate ventilation & illumination

ambient and task illumination, bed, working bench to prepare smears, storage area for sterile material and needles, sink with running water, facilities for proper disposal of waste material (cotton wool/ gauze/sharps) and patients waiting area.

Clinic – Separate Clinic area (if a clinic functions) with adequate space for patient's waiting area and blood collection area if applicable. Good ventilation, illumination, adequate space, working benches, sink with running water, examination bed, disposal of waste material (cotton wool/ gauze/ sharps).

Main Lab – Separate area for blood analyzer machines, for Serology testing and special haematological procedures with good ventilation, light and space and provisions for first aid. All laboratories must have a fire escape. Space for storage of glass slides, stationary, microscopes, reagents and an adequate space for equipment (refrigerator, centrifuge etc).

6.2.2 Microbiology:

Sample processing area and media room must conform to the National guidelines published by the Ministry of Health, Sri Lanka (www.health.gov.lk/pub & reports/NationalGuidelines.htm) and regulations enforced by the Central Environmental Authority, Sri Lanka as appropriate. The Bio safety Manual Produced by the Sri Lanka College of Microbiologists can be referred.

6.2.3 Histopathology:

Specimen reception area – A designated room or area with adequate space and facility for sample accession and related activities including sample identification, application of acceptance criteria, to take the corrective actions and to implement safety measures (fume hoods ect).

References: space requirements

Tissue grossing room- A designated room designed with effective facility for evacuation of formalin vapor with the formalin vapor concentration to be maintained below adequate ventilation, Lighting. Sink with running tap water hand free operable taps, grossing tables with necessary facility for documentation, Equipment required for grossing, close cupboards to keep the sample containers and wet tissue samples. Facility to follow standard procedures for safe disposal of samples and chemicals should be available.

Reference: college guidelines

Main lab should include– Adequate ventilation (air condition), light and adequate space for per person work bench work and relevant standard equipment. Enclosed designated area or cupboard for safe storage of chemicals, First aid box, Storage facility for paraffin blocks, slides, reports and registers.

Electron Microscopy- A separate room shall be allotted for tissue processing with a fume hood for handling osmium tetroxide.
A separate dust-free facility, with air-conditioning shall be available for preparation of specimen and performing electron microscopy.

i. The electron microscopy room shall have:
ii. Facilities in place for temperature control and chilled water supply
iii. Insulated cabling kept away from the work areas
iv. Proper seating should be available to allow for optimal ergometric positioning of the person using the microscope
v. Dark room with adequate ventilation.
vi. Warning light on the door of the dark room indicating usage.

6.2.4 Cytopathology:

i. An examination bed and chair in a designated area or room with sufficient privacy and facilities for Fine Needle Aspiration. Disabled patient access should be accommodated. The laboratory should have adequate light, ventilation and necessary facilities to carry out Fine Needle Aspiration. Disposal of sharps and biological material should be in accordance with the accepted standards.
ii. proper seating should be available to allow for optimal ergometric positioning of the person using the microscope

6.2.5 Immunology:

Separate area (could be in the main lab) should be air conditioned. The laboratory shall have proper lighting, tables, working bench, fridge, proper freezing facilities, and electricity supply (very important to keep antisera at proper temperatures).

Reporting Room – A separate room or area may be in the main lab

6.2.6 Pharmacology:

The laboratory shall Prevent tampering or alteration of samples and ensure security of samples.

6.2.7 Nuclear Medicine:

The Laboratory shall follow Radio Isotopic Requirements of Sri Lanka Atomic Energy Board.

63 **Laboratory Equipment, Equipment calibration and metrological traceability (6.4 to 6.5 of ISO 15189:2022)**

A documented procedure for the maintenance, calibration and performance verification of all test equipment shall be maintained. The equipment shall be calibrated from an accredited calibration laboratory where applicable. The laboratories shall follow SLAB guideline on maintaining Measurement Traceability- (Measurement Traceability Policy on Metrological Traceability of Measurement results- AC-RG(P)-04).

In the case of analytical systems such as automated analyzers the frequency of calibration shall refer to the manufacturer's guidelines. The laboratory shall have a written procedure for calibration of automated instruments. All automated analytical systems such as cell counters, clinical biochemistry autoanalyzer, automated coagulometers and ELISA readers etc., shall be calibrated at least once a year.

Automated haematology analyzers should be calibrated using 'calibrators' provided by the manufacturers. Controls often lack absolute accuracy and are not recommended for use as calibrators. Sometimes, however, calibrators are not readily available and controls with assigned values may have to be used as calibrators. In such cases the laboratory must ensure that the values of the controls have been assigned reliably by a reference method.

Certain items of equipment may be calibrated by laboratory itself without the service of external calibration bodies, provided the laboratories have the necessary reference standards and materials and such calibration procedures do not demand specialist techniques which are outside the capabilities and experience of the laboratory staff. In such cases the laboratory should develop its own procedures for Calibration of test equipment. If the laboratory needs to verify any of the measurements of any test equipment that may be performed using a calibrated reference standard/material following a procedure documented in that respect.

The nominal maximum periods between successive calibrations of general equipment are given in Table 2.

It must be stressed that these calibration intervals depend upon:

a. Ruggedness of the equipment
b. Frequency of use
c. Life of the equipment
d. Quality and periodicity of maintenance, etc.,

Table 2: Calibration and maintenance requirements

Item	Maximum period between successive calibration & checks	Procedure and comments
Autoclaves	One year	*Check on effectiveness of sterilization with each cycle
Balances and scales	One year	Balances with in-built calibration check facility must also have six monthly checks Electronic balances with more than one range must have six monthly checks carried out on all ranges Checks include repeatability checks and one-point check using a known mass close to balance capacity
Biological safety cabinet	One year	*Air Quality -Colony count at least once in a week
Centrifuge	3 years (for small scale laboratories) 2 years (for medium scale laboratories) 1 year (for large scale laboratories)	Tachometer (mechanical stroboscope or light cell type) calibration of the timing device and, where appropriate, the temperature measurement device will be required. In addition, performance testing is recommended for specific applications.
Manometers: Reference Working	Five years One year	Check Fluid every three years Check against reference

Piston-operated volumetric apparatus pipettes and dispensers.	1 year (volumetric apparatus used for preparation of QC material and for manual testing)	AS 4163 For gravimetric checks, volume delivery and weighing under specified conditions must be repeated at least ten times. For adjustable devices check volume delivered at several settings. Delivery of volumes less than 100 microlitre may be verified by spectrometry using a dye solution.
Diluters	Six months	*Check volume delivered at settings in use. Check sample and diluent volumes or dilution ratio and total volume
Thermometers (Liquid in glass, resistance, electronic)	One year	Check against a calibrated reference * Initial check at sufficient points to cover the expected working range followed by six monthly checks at ice-point within the working range Separate thermometer should be used for each refrigerator. The temperature of the refrigerators should be checked daily (morning and afternoon)

Item	Maximum period between successive calibration & checks	Procedure and comments
Haematology Analyzers	Every three months	Calibration to be done at installation and Commercially prepared Controls (Normal & Abnormal) to be done at least once in 3 months.
Coagulation Analyzers	Every three months	Calibration to be done at installation and after every breakdown Commercially prepared Controls and every time the reagents are being changed. Daily in house controls.
Chemical Analyzers	Every three months	Maintenance should be carried out as per the manufacturer's recommendations. Calibration to be done at installation and Commercially prepared Controls (Normal & Abnormal) to be done at least once in 3 months. Calibration should be performed after a repair followed by verification of performance. Daily in house controls
Bone Marrow+ Trephine needle	Daily. To be checked before use	Autoclave daily after use
Slide Staining Machine		Time setting to be checked daily Staining bath level to be maintained
Specimen Rotator		Maintain the speed
Water bath		Monitor temperature daily Change water regularly
Agregometer		Always run with a control Check the Chamber daily

		Check the temperature range and graphs
Electrophoretic Bath		To check pH of solution before use. To check electricity input
Freezers & Refrigerators		Daily temperature checking
ELISA Readers	One year	Should be subjected to performance checks (Lamp check, Integrity check and Absorbance checks) with QCs. Calibration is necessary with each test run. If the lot numbers are changed, verification is also needed.
PCR Machines	One year	
Tissue embedding station	Once in six months	
Microtome		Maintenance 03 months

** Calibrations / Verifications commonly performed by laboratory staff*

pH meter
Calibrate on use with at least two standard buffer solutions appropriate to the expected pH of the sample being tested. A record of the calibration must be kept.

Spectrophotometer and colorimeter
Calibration checks on all spectrophotometers or colorimeters shall be performed with Holmium Oxide filters or colourd solutions (e.g. Dichromate for UV and Hb for Visible ranges) every 3 months. at six months interval. Such calibration shall include checks on absorbance, linearity, matching of cells and must be carried out in accordance with the manufacturer's instructions and/or appropriate procedures using standard/reference materials. A blank and at least two points on the calibration curve must also be checked. These calibrations should be compared over time to detect any system deterioration.

Chromatograph

a. *Gas chromatograph*: Performance shall be routinely monitored during use with certified reference materials.
b. *Liquid chromatograph*: Including high performance liquid chromatograph (HPLC): The total system must be monitored during use with certified reference materials. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (e.g. pumping system and detectors) shall be subject to periodic checks and details shall be recorded.

Electrophoresis
Instrument performance shall be routinely monitored during use with appropriate controls. System components (e.g. electrodes, tank and power supply), must be checked periodically.

Microscopes
Regular cleaning and maintenance of microscopes is essential for satisfactory operation. The stage and lenses shall be cleaned after use and maintenance and servicing shall be carried out by competent personnel.

Temperature-controlled equipment

The performance of temperature-controlled equipment such as water baths, incubators, ovens and refrigerators etc., shall be monitored routinely to ensure compliance with the temperature requirements of test methods. Accordingly, daily recorded checks of the temperature within the load space of these items of equipment shall be maintained. The use of continuous temperature monitors is strongly recommended where temperature control is critical (ex. blood banking). The thermometers used to monitor the performance of temperature-controlled equipment shall be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods. The spatial distribution of temperatures throughout the load space of temperature-controlled equipment shall be checked following installation of equipment and at appropriate intervals thereafter. Temperature recording devices shall be checked at six monthly intervals against a reference thermometer and the results recorded.

6.3.1 Microbiology:

A separate biological safety cabinet, certified at least annually to ensure that filters are functioning properly and that air flow rates meet specifications, must be available for mycobacteriological work and for mycological work.

The laboratory performing fungus culture shall be equipped with heating and cooling (BOD) incubator to meet with the environmental conditions for the isolation of fungi.

Media

Laboratory shall ensure that in-house prepared media are sterile, able to support growth and are appropriately reactive bio-chemically. Therefore, the laboratory must maintain the stock of reference organisms. These should be used to test the media. Blood-based media shall be prepared using appropriate animal blood procured from an authorized source. Sheep blood is recommended.

Reagents/ Kits/ Antibiotic discs

Stains and reagents must be labeled, dated and stored properly and not used beyond their expiry date or if they show signs of deterioration, such as abnormal turbidity and/or discoloration. At regular intervals and whenever new stain is prepared, control smears should be stained.

Stains

Appropriate controls should be used for all stains.

Microscope with Oil immersion objective (100X)

6.3.2 Histopathology:

Tissue Processing

a. Depending on the workload the laboratory shall develop a procedure to change the tissue processing chemicals. Maintain records of chemical change.
b. A log recording of the ‘time setting schedule’ for an automatic tissue processor shall be maintained.
c. Temperature of the wax bath shall be checked and recorded daily.

Tissue embedding

a. SOPs should be available for embedding of different types of tissues (ex. Skin, cysts, Lymhnodes, hollow organs)
b. Temperature of the wax heating chamber and cooling plate should be checked and recorded daily in case of automated machine and wax heating oven in case of manual system.
c. Standard size tissue embedding moulds should be used

Microtome

a. Initial setting of the microtome should be recorded including angle of the blade, thickness of the sections etc.
b. Appropriate adjustments for different types of tissues should be followed according to the SOPs
c. Microtome with non-disposable knife shall have a safety shield.

Slide warming stage

Temperature of slide warming stage shall be checked daily

Flotation bath

a. The fluid in the flotation bath shall be changed at least once a day and should be documented
b. The surface of the water bath shall be skimmed regularly during section cutting to remove floaters.

Cryostat

Has to be calibrated and the temperature has to be set daily and should be documented

6.3.3 Cytopathology:

Microscopes used for screening shall have 4 X, 10 X and 40 X objectives. Spare bulbs and fuses shall be available in the laboratory.
All equipment such as centrifuges capable of creating bio-hazardous aerosols should be used in extractor cabinets or rooms fitted with extractor facilities.
The laboratory performing Cytopathology tests must use cytocentrifuge for processing the samples and cell blocks should be prepared whenever possible.

6.3.4 Flow Cytometry

Diagnostic flow cytometry should be performed on flow cytometers made by standard companies that provide precise and verifiable procedures for operating and evaluating the performance of the machine. This would include procedures for calibration of the flow cytometer for instrument setup, optical alignment, test specific settings, colour compensation and daily performance, monitoring and verification. The flow cytometers must be operated and maintained exactly as per the standard operating procedures prescribed by the manufacturers.

Some important points regarding the instrument hardware and software that is being used for diagnostic work are as follows:

The instrument should be optically pre-aligned and pre-calibrated for optimal fluorescence and

scattered light outputs i.e. the operator should not be able to change the alignment or calibration of the instrument without factory trained experts of the instrument.

The laboratory should use an optimal number and combination (panel) of antibodies that are able to distinguish between the major types and subtypes of leukemia/ lymphoproliferative disorders. The laboratory should determine the optimal concentration/dilution of an antibody for each assay before using it as a reagent for diagnosis. Laboratory should have documented procedure for reducing the effects of non-specific binding of antibodies to cells being tested.

6.3.5 Immunology:

Freezers have to be maintained with uninterrupted electricity supply. pH meter has to be adjusted daily.

6.4 Reagents and consumables (6.6 of ISO 15189:2022)

All reagents and consumables shall be used in accordance with the applicable test methods and relevant legal requirements of the country of use. The laboratory shall ensure traceability of all reagents, consumables, and reference materials used.

All reagents, consumables, stains, media, kits and antimicrobials should be stored as recommended by the manufacturer and used within their indicated expiry dates. The label should bear the following information: content and quantity, concentration or titer, date received/prepared, date of opening, storage requirements and expiry dates, wherever applicable.

The laboratory shall use appropriate controls for reagents, stains, media, kits, antimicrobials, etc to check their performance where a built-in control does not exist. For use of commercial reagents and controls manufacturer's instructions should be complied with.

All reagents/ stains/ media/ kits/ antimicrobial discs shall be procured from standard reputed sources. Each lot of reagents shall be checked against earlier tested in-use reagent lots or with suitable reference material before being placed in service and the results should be recorded. Each lot of antibiotic sensitivity discs should be checked for activity/potency before being placed in service and at least weekly thereafter with reference strains. Reusable specimen containers should be inspected regularly, especially the caps of bottles and tubes for missing or worn out liners. Anaerobic jars, autoclaves and hot air oven should be checked by chemical and/or biological controls.

6.5 Service Agreements (Cl. 6.7 of ISO 15189:2022)

When reviewing service agreements, laboratories shall ensure that the examinations requested relate to the needs of customers for the intended purposes. As far as practicable, laboratories should give advice to customers and help them determine their needs. In cases samples would be further referred to another laboratory for confirmation or for supplementary tests, circumstances and/or conditions upon which such referral takes place shall be made known to the customers before they enter into service agreements.

In the case where a laboratory is a part of a hospital and provides in-house services to the hospital, internal communication between user clinicians and the laboratory can be considered as the agreement and the requirements of this clause apply. The communication may be in the

form of memorandum, manual, letter, emails, etc.

6.5.1 Agreement with POCT Operators (Cl. 6.7.2 of ISO 15189:2022) shall be applied

6.6 Externally provided products and services (Cl. 6.8 of ISO 15189:2022)

There are two commonly encountered situations where a laboratory needs to seek external services and supplies:

a. Purchase of consumables or perishable items, e.g. media, chemical reagents and glassware: Records shall be kept of the different brands of those items which bear a critical influence on the examination results. The records should, where appropriate, include results of the acceptance tests on each new batch prior to use. When a particular brand shows an undesirably high rejection rate, consideration should be given to exclude it from the list of acceptable source of supplies.

b. Purchase of equipment:
Separate records shall be kept for each manufacturer supplying major items of equipment. The records should include results of the acceptance tests and the subsequent maintenance history of their products. Manufacturers whose products consistently do not meet their stated performance specifications and/or show undesirably high proportion of instrument down time and/or are not supported by good after-sales service should be noted and their names removed from the list of acceptable suppliers.

c. Purchase services:
In a medical/clinical laboratory context, "purchased services" refers to any external services that the laboratory obtains from outside organizations or providers to support its operations, but which are not performed directly by the laboratory's own staff or facilities

6.7 Pre-examination processes (7.2 of ISO 15189:2022)

Specific instructions for the proper collection and handling of primary samples shall be documented. This shall be applicable for the collection facility at the main laboratory and the sites other than the main laboratory viz., collection centers. The procedures should include specific instructions for sample collections to be followed at the collection centers.

6.7.1 Haematology:

FBC specimens must be checked for clots (visually, by applicator sticks, or by automated analyzer histogram inspection or flags), significant *in-vitro* haemolysis and interfering lipaemia before analyzing the sample. FBC processing, either automated or manual, should be done within 6 hours provided samples are stored at room temperature.

Specimens for coagulation tests and ESR must be checked for presence of clots, haemolysis and for accuracy of volume. All the coagulation tests must be performed within 4h of collection. All APTT based tests should be done on properly separated platelet poor plasma. If delay is expected plasma should be separated and kept frozen until test can be performed (at -20^{0}C for up to 2 weeks or at - 70^{0}C for up to 6 months). PT & INR can be performed from separated plasma kept at room temperature up to 8- 12 hours.

When the room temperature in not controlled and goes beyond 29^{0}C, plasma separation for coagulation testing should be done in a refrigerated centrifuge [specially for APTT]. Laboratories need to check temperature inside the centrifuge after centrifugation at random intervals if non

refrigerated centrifuge is used to separate plasma. Tests for thrombophilia screening should be done on fresh samples.

All EDTA specimens preferably should be stored on a rotator until analyzed. If not, samples should be homogenized properly by ten complete gentle inversions immediately before aspirated in autoanalyzer.

Blood smears for blood pictures should be prepared from fresh sample of anticoagulated blood or using a finger prick blood drop. If not, blood smears has to be prepared within 2 hrs from the time of collection of the sample.

All the examination procedures should be taken from standard guidelines or methods traceable to standard guidelines such as WHO, ICSH & SLCH etc.

The methods of validation of automated FBC results should be available in each laboratory. The indications for reviewing a blood smear should be defined and documented. The method of verification of low platelet counts should be available when automated analyzer reports generate low platelet counts.

ESR should be performed in an area free of interferences such as vibrations, direct sun light & direct wind currents etc.

Blood film examinations: The blood film shall exhibit satisfactory quality for, staining properties, minimal debris and distribution plus morphology of cells. Where appropriate an estimation of cell counts should be made from the blood film and correlated with abnormal counts reported.

6.7.2 Microbiology:

Specimens for culture and sensitivity must be processed immediately after collection. Collection, transport and storage of specimens should conform to the Laboratory Manual published by the Sri Lanka College of Microbiologists.

6.7.3 Histopathology:

*(*In Histopathology *P*re analytical phase include: Sample collection, Transport and Accession)

a. Specimen should be adequately fixed in 10% formal saline.
b. Ideally the formal saline volume should be 10 times more than the specimen
c. A wide mouthed container, allowing the fixed tissue to be removed without causing damage to tissue, should be used.
d. The container should have a well fitting lid.
e. The laboratory is responsible for ensuring the strength of formal saline issued to the specimen collecting points.
f. Specimens in formal saline should be transported safely.
g. Accession of specimens in the laboratory should be done by an authorized person and he or she should ensure the correct identification of sample (putting the laboratory serial number), completeness of request form and adequacy of formalin in strength and quantity.
h. Accepting or rejecting of samples should be according to documented procedure.

Recommended fixatives may be used for different types of tissues (For renal, and testicular biopsy).

Frozen sections – Prior arrangements with the laboratory is mandatory. Specimen

should reach the lab as soon as possible ideally within 05 minutes of surgery. A responsible person must accompany the specimen. Contact number of the surgeon should be stated in the request form. High risk samples (HIV, Hepatitis B and C) shall be labelled and identified.

6.7.4 Cytopathology:

i. The procedure describing the sampling requirement for each specimen shall be readily available at all submitting locations (laboratory/ clinic/ hospital) and shall contain the following information:
    a. Preparation of patient for sampling.
    b. Consent form for Fine-Needle Aspiration (FNA).
    c. Collection techniques.
    d. Specimen identification and labeling.
    e. Fixation requirement e.g. anticoagulant used, fixative (wet fixed and/ or air dried) and storage requirements.
    f. Transportation instructions.
    g. Safety precaution for all of the above (with special reference to HIV and Hepatitis).
    h. All laboratory staff handling infected material shall be vaccinated against HBV.

ii. Where possible, FNA shall be carried out by Pathology trained personnel (clinicians/radiologists may perform FNA, following documented procedures as provided by the laboratory and sign the requisition form).

iii. A request form should accompany every specimen and contain the following information:
    a. Full demographic data
    b. Relevant clinical history, clinical findings and provisional diagnoses
    c. Anatomical site of collected specimen
    d. Date and time of specimen collection
    e. Information regarding previous cytology report
    f. Contact details of the referring surgeon/physician.

iv. For gynecological cytology the request form shall also contain:
    a. Details of menstrual phase and hormonal status
    b. Details of hormone therapy
    c. Details of contraception
    d. Details of previous surgery

v. For intra-operative imprint/ aspiration cytology, the request form shall also contain detailed surgical information observed at the time of procedure.

Flow Cytometry

Sample Handling

Blood/ bone marrow specimens collected in EDTA are stable up to 24h and in heparin up to 72h at room temperature. Samples must be transported and stored at ambient temperature (10-30^{0}C).

Sub-optimal and unacceptable samples include:

- Presence of clot, hemolysis, improper container
- Samples received beyond 48h after collection or if inappropriately labeled
- Samples received beyond 24h showing <80% viability on being tested by trypan blue test.

Presence of malignant cells should be verified microscopically by a pathologist prior to analyzing for suspected malignancies.

6.7.5 Storage period of examined specimen

All the samples should be retained until the reports are signed out. The examined specimens shall be stored for re-examination and/ or additional tests for a minimum period as specified below:

Clinical Pathology:
Semen morphology slides – 1 week

Chemical Pathology:
CSF and Body Fluids until the reports reach the physician.

Clinical Biochemistry:
7 days at 2-8^{0}C
Special Biochemical, Endocrine and Tumor Marker tests – 3 months at -20^{0}C or specified in method

Haematology:

Full Blood Counts: 24 hours at 2-8 ^{0}C
Coagulation screening test [except PT, factor VII assay and lupus anticoagulant] 4 hours at 2-8 ^{0}C
For PT, factor VII assay and lupus anticoagulant room temperature for 2 hours Haemoglobin electrophoresis and HPLC – 1 week at 2-8 ^{0}C or longer below -20 ^{0}C Bone Marrow slides & Trephine blocks – These paraffin-embedded tissue blocks are stable at room temperature indefinitely (standard retention is often 10–20 years) if kept in a dry, pest-free environment *
HLA typing cell preparation – 3 days Blood Picture slides – 1 Week
Note: these storage conditions are specified as per Practical Haematology by Dacie and Lewis. Ed 12th Ed

If different storage conditions are specified, the laboratory shall provide reference data for the used method/conditions.

* The laboratory may consider giving the original slides to patients on request for obtaining second opinion or for treatment elsewhere. The laboratory shall have a documented procedure and maintain records of the same. However, attempt should be made to retain at least one representative primary slide on which the diagnosis was based for review during the follow up.

Histopathology:
Specimens – minimum of 21 days
Slides – minimum of 5 years**
Wax blocks - minimum of 10 years

Cytopathology:
Fluids –minimum 48 hours at 2-8^{0}C
Slides – 5 years*

A sample can be kept for a longer period if it is necessary for further characterization of the pathology or for educational purpose (with the consent of the patient).

** The laboratory may consider giving the original slides to its patients on specific request for obtaining second opinion or for treatment elsewhere. The laboratory shall have a documented procedure and maintain records of the same. However, attempt should be made to retain at least one representative primary slide on which the diagnosis was based for review during the follow up.

Molecular Biology:
Blood samples for karyotyping – 6 days at 2-8^{0}C
Extracted DNA – 5 years at -20^{0}C
Extracted RNA – 5 years at -70^{0}C
Molecular diagnostic gel pictures/ qPCR amplification plots – 5 years

Flow Cytometry:
Follow the instructions of the method.

6.8 **Examination processes (Cl. 7.3 of ISO 15189:2022)**

6.8.1 Clinical Pathology:
All the rapid testing Kits/devices should meet the criteria laid down by the CDDA. Such testing kits or devices used should be registered with CDDA or the laboratory should provide evidence that such testing kits or devices have been evaluated and approved for use by an acceptable authority in the country of manufacture/origin.

6.8.2 Clinical Biochemistry:
Follow the WHO recommended methods, IFCC or any other validated method. Modifications should be followed by the evaluation of the method under in-house conditions.
The chemicals /reagent kits should be stored under manufacturers' recommendations.

6.8.3 Haematology:
CBC specimens must be checked for clots (visually, by applicator sticks, or by automated analyzer histogram inspection or flags), significant *in-vitro* haemolysis and interfering lipaemia before reporting results. CBC processing, either automated or manual, should be done within 6 hours.

Specimens for coagulation tests and ESR must be checked for presence of clots. Coagulation tests must be performed within 4h of collection. If delay is expected plasma should be made platelet-free and kept frozen until test can be performed (at -20^{0}C for up to 2 weeks or at -70^{0}C

for up to 6 months).

Specimens for thrombophilia screening should be done on fresh samples. All EDTA specimens to be on a rotator until analyzed.

All specimens for special tests to be carefully checked before analysis. Bone marrow slide handling & staining to be done at a special desk.

Blood film examinations: The blood film shall exhibit satisfactory quality for, staining properties, minimal debris and distribution plus morphology of cells. Where appropriate an estimation of cell counts should be made from the blood film and correlated with abnormal counts reported.

6.8.4 Microbiology:

The methods recommended are as follows;

1. The methods recommended in the Laboratory Manual published by the Sri Lanka College of Microbiologists.
2. WHO/CDC
3. Commercial Kits – Manufacturers Recommendations
4. Inhouse clinical validation
5. Published articles in peer reviewed Journals
6. Standard Textbooks

6.8.5 Histopathology (Analytical phase includes processing and interpretation of slides)

a. Cut up (Gross examination and taking representative sections for examination) – Has to be done strictly under the guidance of a Histopathologist, by a qualified trained medical officer or by a Histopathologist).
b. Cut ups should be done in line with standard guidelines and guidelines should be available at the working bench in a practicable version.
c. Tissues taken should be put into cassettes directly and should be identified in a standard way.
d. Processing of the tissue should be performed in a processor that is maintained as stated above.
e. Embedding, tissue cutting and staining of slides should be carried out according to standard methods. Deviations from the standard methods should be verified and validated in the laboratory.
f. A quality control tissue section to assess the quality of stain should be used prior to every batch of slides submitted for reporting.
g. Mounting and labeling of slides for reporting should be done in line with standard guidelines.
h. A quality check should be performed on slides and slides with technical errors should be marked prior to submission for reporting.
i. If any alterative type of alcohol is used its effectiveness for the procedure has to be validated.
j. Highly infective / high risk material (Eg. Prion Disease) has to be handled according to WHO recommendations.
k. Reporting should be in line with standard Guidelines (National or international).
l. Use of ancillary tests is recommended to further characterize the pathology and to increase the accuracy of the diagnosis.

m. The laboratory should have provisions to obtain peer view opinions on regular basis with documentary evidence.
n. Participation in multidisciplinary meetings on a regular basis with documentary evidence of cases discussed has to be recorded.
o. Laboratory should develop policy for obtaining second opinion and referral system of cases in collaboration with laboratory management.

6.8.6 Nuclear Medicine:

The Laboratory shall follow Guidelines prepared by Sri Lanka Atomic Energy Board.

Biological Reference Interval should be age- and sex- specific and established by the laboratory for the method used. If it is not practical to establish the biological reference interval for a particular analyte the laboratory should carefully evaluate the published data for its own reference intervals and retain documentation of this evaluation.

6.8.7 Evaluation of measurement uncertainty (Cl. 7.3.4 of ISO 15189:2022)

Currently SLAB accepts imprecision of test results as it is most relevant to interpret MU with the caution that quality control materials may not totally reflect the analytical behaviour of patient specimens. This imprecision is most easily derived from long-term internal quality control (QC) data, calculated as standard deviation (SD) or coefficient of variation (CV%). For recording estimates of uncertainty of measurement, the imprecision should be documented as the 95% confidence interval (± 1.96 SD; or ± 1.96 CV%). Depending on the range of reportable values and clinical use of the test, it is appropriate to record the estimate of uncertainty of measurement (imprecision) at more than one level of quality control, and a minimum of six months internal QC data should be used to calculate routine imprecision and updated annually.

It should be noted that imprecision derived from the performance of a laboratory in an external quality assurance programme is not recommended for estimating uncertainty of measurement, because generally far fewer data points are available on which to base the uncertainty estimate relative to the number available from internal QC.

The Guide to the Expression of Uncertainty in Measurement (GUM) is generally accepted worldwide as the master document describing the theory and implementation of uncertainty of measurement. It outlines procedures for estimating the standard uncertainties of measurement of a well characterized measurand.

6.8.8 Ensuring the validity of examination results (Cl. 7.3.7 of ISO 15189:2022)

Internal quality control (IQC) (Cl. 7.3.7.2 of ISO 15189:2022)

The laboratory shall design and implement internal quality control systems that verify the attainment of the intended quality of results. If the Internal Quality Control material has supplied from the reagent, the supplier's Quality Control material is accepted with proven traceability or third party Quality Control material with proven traceability. Daily Internal Quality Control to be done according the following table;

Situation	Method
Clinical Chemistry	Low and High Quality Control to be used
Immunoassay	All three Quality Controls to be used
Automated analyzers	Repeat at least one Quality Control at every 100 samples.
Manual methods	With every batch Quality Control Material to be done Chemistry: Beginning and End Immunoassay: 3 Quality Controls and at least one to cover every raw

Haematology:

The laboratory shall design and implement internal quality control systems and external quality assurance that verify the attainment of the intended quality of results using commercially available QC material. Minimum of two levels of IQC should run daily and in addition, the test performance should be monitored using alternative IQC methods where applicable.

Internal Quality Controls by using alternative methods can be carried out by using methods recommended in standard textbooks.

For FBC number of samples to be tested for alternative IQC testing [test duplication and testing retained samples is as follows.

1. For laboratories receiving less than 100 numbers of samples at least 3 samples randomly selected from normal, high and low values shall be used for IQC monitoring.
2. For laboratories receiving more than 100 numbers of samples, additional one random sample IQC for every 50^{th} sample or a portion.

Blood smears should be reviewed to verify WBC/ DC and platelet count when necessary. There should be a written procedure for release of abnormal analyzer reports.

For further guidance on Quality Control Systems and methodologies that could be adopted in different tests of haematology, reference could be made to Guidelines published by the College of Pathologists/Haematologists Sri Lanka.

Histopathology

1. Periodic review of slides for the quality of processing and staining with documentary evidence,
2. Conducting regular audits etc.
3. Random case review (blind reporting of random cases by same person and by a different person) with documentation
4. Comparison and correlation with other reports (frozen, cytology and histology)

Microbiology

Each laboratory must have Standard operating procedures (SOPs), to cover each procedure in the laboratory.

Quality control (QC) must cover all aspects of every procedure within the department. The QA of the pre-analytical, analytical, and post-analytical stages of microbiological procedures should be incorporated in SOPs of microbiology laboratory.
SOPs for pre-analytical stage need to describe selection and appropriate use of microbiological investigations, proper filling of request form, collection and transport of specimens, and checks to ensure that the specimen and request form reach the laboratory and are entered in the register.

SOPs for analytical stage should discuss, detailed procedure for examining different specimens, staining techniques and QC of stains, aseptic techniques and safe handling of infectious material, preparation and QC of culture media and preservation of stock strains, reading and interpretation of cultures, techniques used to identify pathogens, antimicrobial sensitivity testing and QC of procedures and antibiotic discs, cleaning and QC of equipment used in microbiology laboratory, QC of equipment used in the microbiology laboratory, disposal of specimens and cultures, cleaning of glassware, plasticware, etc. and sterilization procedures and their control.

External quality assessment (EQA) / Proficiency testing (PT) (Cl. 7.3.7.3 of ISO 15189:2022)

Microbiology

Quality Control of Equipment
All equipment used for tests, having a significant effect on the accuracy of result of the test should be calibrated before being put into service and on regular intervals thereafter. For each item of equipment there should be clear operating and cleaning instructions, and service sheets. Regular cleaning, servicing and maintenance are essential if the equipment is to remain in good working order and safe to use. A brief list of some of the equipment, the monitoring procedures to be carried out, and the frequency and tolerance limit is given in table 1.

Equipment	Monitoring	Routine care	Technical maintenance and inspection
Autoclaves	1. Check and adjust water levels before each run. 2. Record pressure, temperature and time after reaching the steady temperature for each run. 3. Use autoclave strips daily to assess uniform steam penetration. 4. Use biological indicator (*Bacillus stearothermophilus* spores) once a month to assess performance. 5. Get the autoclave calibrated at set intervals defined by the laboratory.	1. Clean and change water monthly. 2.	Every six months. As per the Larger scale laboratory frequency of use to be considered when consider the frequency
Incubators	1. Record the temperature with a calibrated thermometer daily. (Tolerance limit -35+/-2 ^{0}C for bacteriology) 2. Get the incubator calibrated at set intervals defined by the laboratory	Clean inside walls and shelves monthly. This should be done more frequently once a week	Every six months.
Refrigerators	1. Record the temperature with a calibrated thermometer daily. (Tolerance limit -2 ^{0}-8 ^{0}C) 2. Get the refrigerator calibrated at set intervals defined by the laboratory	Clean after unplugging every 2 months.	Every 6 months.
Microscopes	Check alignment of condenser monthly.	1.Wipe lenses with lens paper after each day's work. Protect with dust cover when not in use. 2.Clean and lubricate mechanical stage weekly.	Annually.
Centrifuges	Get it calibrated using a tachometer at pre-defined intervals.		Every six months.
Hot-air oven	Record temperature and time for each run.	Clean inside monthly	Every six months.
Safety cabinets	Check airflow rates at defined intervals	Clean with alcohol wipe and use the UV light after each use.	Every six months.

Calibrated loops for urine culture or sputum culture	1. Should use calibrated loops with certificates. 2. If the loops are reused, verification has to be performed at specified intervals with a unused calibrated loop.		
Pipettes/Micro pipettes	Calibration should be done at specified intervals.	Disposable tips should not be reused.	

Quality control of media:

Sterility and performance of media have to be checked and recorded with each batch prepared. Labelling of media should be adequate to trace the type of media, date of preparation, person responsible and the batch of media used.

Table 2 : Quality control of commonly used media: suggested control organisms and expected reactions		
Medium	**Control organism**	**Expected reactions**
Blood agar	Gp. A Streptococci *S. pneumoniae*	Good growth, β-haemolytic Good growth, α-haemolytic
Bile-esculin agar	*Enterococcus* species, β-haemolytic *Streptococcus*, not Group D	Good growth, black No growth
Chocolate agar	*H. Influenzae* *N. gonorrhoeae*	Good growth Good growth
Christensen urea agar	*Proteus mirabilis* *Klebsiella pneumoniae* *Escherichia coli*	Pink throughout (positive) Pink slant (partial positive) Yellow (negative)
Simmon's citrate agar	*K. pneumoniae* *E. coli*	Growth or blue colour (positive) No growth, remains green (negative)
Deoxyribonuclease	*Serratia marcescens* *E. cloacae*	Zone of clearing (add 1N HCl) No zone of clearing
Motility (semisolid agar)	*P. mirabilis* *K. pneumoniae*	Media cloudy (positive) No feather edge on streak line (negative)
MacConkey agar	*E. coli* *P. mirabilis*	Pink colonies (lactose positive) Colourless colonies, no spreading
Sucrose	*E. coli* *N. gonorrhoeae*	Yellow (positive) No colour change (negative)
Maltose	*Salmonella* species *N. gonorrhoeae*	Yellow (positive) No colour change (negative)
Lactose	*N. lactamicus* *N. gonorrhoeae*	Yellow (positive) No colour change (negative)
Lysine	*K. pneumoniae* *Enterobacter sakazakii*	Bluish (positive) Yellow (negative)
Arginine	*E. cloacae* *P. mirabilis*	Bluish (positive) Yellow (negative)
Ornithine	*P. mirabilis* *K. pneumoniae*	Bluish (positive) Yellow (negative)
o-Nitrophenol- *p*-D galactopyranoside (ONPG)	*Serratia marcescens* S. Typhimurium	Yellow (positive) Colourless (negative)
Phenylalanine deaminase	*P. mirabilis* *E. coli*	Green (add 10% $FeCl_3$) No colour change (negative)
Salmonella-Shigella (SS) agar	S. Typhimurium *E. coli*	Colourless colonies, black centre No growth
Voges-Prauskauer	*K. pneumoniae* *E. coli*	Red (add reagents) No development (negative)
Xylose-Lysine-Dextrose (XLD) agar	*Salmonella* species *E. coli* *Shigella* species	Red colonies (positive lysine) Yellow colonies (positive sugars) Transparent colonies (negative)

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Quality control of reagents:

All the reagents should be labelled to give the date of preparation, date of expiry and person responsible along with the name of the reagent. The performance of the reagents should be checked using appropriate control strains and recorded after preparation of reagents and at defined intervals thereafter.

All chemicals used for media and reagents should be labelled to indicate the date of opening and the date of expiry.

Quality control of tests:
All the tests performed for identification of bacteria should be checked by using appropriate positive and negative controls.

Quality control of antimicrobial sensitivity tests:
The quality control of antimicrobial sensitivity testing should be done according to the method of antimicrobial sensitivity testing used.

Whenever formal interlaboratory comparison programmes are not available, the laboratory shall adopt mechanisms to determine the acceptability of procedures not otherwise evaluated. *Eg:* Sending out randomly selected reported cases to recognized third party pathologist and comparing the original report with the first pathologist in Histopathology

The effectiveness of the quality control programmes shall be measured and be included in the management review of the laboratory.

For further guidance on Quality Control Systems and methodologies that could be adopted in different areas of medical laboratory testing, reference could be made to according to National Guidelines

6.9 Post-examination processes (Cl. 7.4 of ISO 15189:2022)

Processed samples should be properly stored for a period specified by the quality system before disposal to allow easy retrieval in case of need, such as for confirmation of patient's information displayed on the primary sample. When samples are disposal of, care shall be taken to protect patient's confidential information.

6.9.1 Reporting of results (Cl. 7.4.1 of ISO 15189:2022)

Laboratories should report results of normal controls when they are necessary for the proper interpretations of the examination results.

There shall be established protocol to review clinically significant examination results. Moreover, there shall be a hierarchical method of review of examination results, that is, a sequential review of the same specimen, when indicated, by individuals with increasing levels of experience and/or responsibilities. Evidence of such activities shall be recorded.

For services accredited for performing examinations only, the laboratory shall fully understand its limitation. It shall, where necessary, state on the report that clinical interpretation by a qualified pathologist is recommended.

Where possible and relevant, age- and sex-specific biological reference intervals should be provided in the report. When they are relevant but not provided on the test reports, appropriate comments should be provided on the reports. Generally, such reference intervals shall be validated or established by the laboratory. If a reference interval study is not possible or practical, then the laboratory shall carefully evaluate the use of published data or data provided by the equipment manufacturer for its own reference intervals, and retain record of this evaluation. The number of significant figures used for reporting a test result shall match the measurement uncertainty of the result.

6.9.2 Result review and release (Cl. 7.4.1.2 of ISO 15189:2022)

The laboratory shall establish critical limits for tests, which require immediate attention for patient management. Test results in the critical limits shall be communicated to the concerned after proper documentation.

Haematology:

Prothrombin Time results should contain the time taken by the patient specimen to clot and mean normal prothrombin time (MNPT) and the International Normalized Ratio (INR). MNPT (geometric/arthematic mean of prothrombin time of 20 normal healthy individuals) should be determined for every new lot of reagents, type of reagent and the instrument used. The INR must be appropriately adjusted for every new lot of prothrombin time reagent, types of reagents and the instrument used. Biological Reference Intervals show significant differences with each lot of reagents, type of reagent, technique and the instrument used and should be determined for each of the situations if the laboratory uses more than one system. The INR/ Ratio stated in the literature is unsuitable for reporting the prothrombin time results.

Full Blood Count reports of analyzer to be checked if necessary, with the slide and rechecked with clinical data if necessary. All Bone marrow slides to be checked only by an authorized person and must adhere to the reporting format stated by WHO or any other authority.

Histopathology:
post analytical phase of *Histopathology include* generation, release of reports, storage, disposal of samples, blocks, slides and retention of test results.

1. The names of the person reporting the macroscopic and microscopic findings along with signatures shall be entered on each report.
2. There shall be adequate description of the macroscopic/ microscopic findings.
3. Report should be in accordance with recent terminology/ classification, grading, scoring, and relevant information necessary for disease management. Report shall also mention all additional tests performed such as special stains, immuno-histochemistry etc.
4. All reports shall be checked for accuracy by the pathologist before authorizing and issuing printed or electronic reports.

5. Reports should be without transcriptional errors.
6. There should be documented procedure for dispatching of reports.
7. Storage of reports material and data should be done in standard ways.
8. Safe disposal of reports (hard copies and electronic material) should be done according to guidelines of central environmental authority regulations.
9. The average turnaround time for issue of reports should be 07 days, but for larger specimens & tissues which need special examinations the turnaround time can vary (10-14 days). Reports including results of special tests, the time period 10-14 days. For very urgent cases the report shall be made available within *24* - 48 hours. If a report is delayed due to a particular and acceptable reason (second opinion, special procedures) an interim report should be issued. Final report should be issued in a reasonable amount of time depending upon the degree of specialization and consultancy needed.
10. When the examination of a permanent section is preceded by frozen section and/or followed by other diagnostic modalities like immuno-histochemistry, *in-situ* hybridization, the final report shall also include these results with interpretation.

Cytopathology:

1. A pathologist shall review and sign all cervical smears from the screening programme screened by a cyto-technologist recorded as abnormal.
2. Explanatory notes shall accompany any unsatisfactory or equivocal report.
3. The turnaround time shall not exceed 3 working days.
4. For intra-operative cytology, the smears should be stained and interpreted within 20 – 30 minutes and the result communicated immediately to the surgeon.
5. In case of reports with abnormal cytologic findings, the pathologist should make recommendations regarding further clinical/histological evaluation, where relevant.

6.10 Nonconformity work (Cl. 7.5 of ISO 15189:2022)

When a nonconformity occurs, the laboratory must take direct action to address the problem. As specified in ISO 15189 Clause 7.5. Unlike a simple "fix" (correction), a corrective action is designed to prevent the problem from happening again by addressing its root cause.

6.11 Control of data and information management (Cl. 7.6 of ISO 15189:2022)

The laboratory shall pay particular attention to protection of patient confidentiality if patient reports could be transmitted via internet. Storage of patient database with confidential information on standalone computers with accessibility to internet is not recommended. There shall be a system to verify correct data transmission and proper functioning after computer downtime or maintenance.

6.12 Control of records (Cl. 8.4 of ISO 15189:2022)

Each laboratory shall maintain a record system designed to suit its particular requirements. The system shall be in compliance with this document but need not be an elaborate one.

Technical records shall include all original observations and raw data and provide a traceable link between the examined specimen as received and the report which is eventually issued. This applies equally to computer and manual record systems. If a laboratory uses a Laboratory

Information Management System (LIMS), the system shall meet all the relevant requirements, including audit trail, data security, safety and integrity, etc. It shall be fully validated and records of validation shall be maintained. Laboratories shall keep back-up copies of electronic records within their retention period. They shall also have a system to ensure that electronic records remain accessible within that period even though the hardware and software of their computer system are being updated from time to time.

The system shall allow for ready retrieval of original observations and data pertinent to any issued report.

The record system shall include ready access to the following detailed information:

i. full description of each sample examined;
ii. identification of the examined sample;
iii. identification of examination method used;
iv. identification of equipment and reference materials used;
v. original observations and calculations;
vi. identification of persons performing the work;
vii. a full copy of the issued report or certificate.

Original observations shall be recorded immediately into bound notebooks, or onto properly designed proforma worksheets. Where data processing systems are used, records of raw data shall be retained unless data are (electronically) fed directly into the processing system. Evidence of counterchecking data transcribed from recorded raw data shall be available.

Sheets of plain paper shall not be used, not only because they are easily lost or discarded, but also because they create a less disciplined approach to the recording of information

Errors in calculations and incorrect transfers of data are major causes of incorrect reports. Calculations and data transfers shall be checked and signed or initialled by a second person. It is desirable to design workbooks and worksheets so that there is a dedicated place for the signature of the checking person.

The laboratory shall decide the retention time of records as per the national, regional and local regulations. However, SLAB requires following minimum retention time for ensuring the quality service and patient care:

Minimum period for retention of test reports (electronic /hard copy):

Particle Cell counter data	01 week
Molecular diagnostic gel pictures/qPCR amplification plots	05 years or as per the country law
Flow cytometry/ Immunophenotyping data	06 months (values only)
Electrophoretogram	01 year
Haemoglobin HPLC data	01 year
Coagulation calibration/ standard graph	01 week
Table/ chart of daily values of internal quality control	01 year
Histopathology, Cytopathology, Molecular Biology	10 years (or depending on the availability of storage facilities) or as per the country law

Bone Marrow reports	05 years or as per the country law
Blood Pictures	06 Months
Other disciplines	01 week

6.13 **Actions to address risks and opportunities for improvement (Cl. 8.5 of ISO 15189:2022)**

Requires medical laboratories to integrate risk-based thinking into their management systems. Laboratories must identify, evaluate, and mitigate risks while seizing opportunities to enhance service quality and patient safety

Prevent issues: Stop nonconformities before they occur.
Optimize outcomes: Improve laboratory efficiency and clinical efficacy.
Protect patients: Minimize the risk of diagnostic errors.
Drive improvement: Turn operational insights into system enhancements

Identification Review total testing phases (pre-examination, examination, post-examination). The laboratory shall record decisions made and actions taken on risks and opportunities.

6.14 **Evaluations (Cl. 8.8 of ISO 15189:2022)**

6.14.1 Quality indicators (Cl. 8.8.2 of ISO 15189:2022)

The laboratory shall incorporate salient quality indicators for monitoring its performance. This shall describe the evaluation of various aspects of a laboratory's function such as but not limited to the following:

- sample collection and identification
- transportation and processing
- analysis and reporting of results
- turnaround time
- complaints
- downtime of processes
- uncertainty of measurements
- performance in PT / EQA scheme

6.14.2 Internal audits (Cl. 8.8.3 of ISO 15189:2022)

The laboratory shall ensure that pre-examination, examination and post-examination processes are all covered during its internal audit along with the other processes including primary sample collection and POCT if applicable. Internal audit shall be conducted at least once in 12 months.

6.15 **Management Review (Cl. 8.9 of ISO 15189:2022)**

The overall purpose of management review is to evaluate past and present performance, in order to develop strategies that will optimize the laboratory's continuing contribution to patient care. A management review must occur at least once each year. Some laboratories may find it convenient to review aspects of performance at different times during the year or to review each discipline/area of operation separately, but it is important that the laboratory director is able to collate all relevant information to form a coherent, documented overview.

7. POINT OF CARE TESTING (POCT) (Annex A of ISO 15189:2022)

Point of Care Testing (POCT) refers to testing performed nearer to the patient and patient bedside. This includes POCT devices used in hospital settings irrespective of its location that excludes devices used for patient self-testing and those in the central testing laboratory.

Patient self-testing is excluded, but elements of this document may be applicable.
NOTE 1 ISO/TS 22583 provides guidance for non-laboratory supported services.
NOTE 2 ISO 15190 and ISO 22367 provide guidance on safety and risk aspects of POCT.

Based on the complexity of POCT device, categorization is as follows:

Category based on complexity	Device	Type of results	Example
Low	Cassettes or single use strips or card test	Qualitative or semi quantitative; Manual reading of results	Pregnancy card test Fecal occult blood test urinalysis
Moderate	Moderately complex instrumentation	Qualitative or semiquantitative Or quantitative; Device display of results	Automated urinalysis instrument, electrolyte analyzer, HbA1c analyzer Glucometer
High	Multiple analytes, multiple cartridges with multitude of internal parts and interface capabilities	Quantitative results; Device display of results	Blood gas analyzer Complete blood counter (CBC), Cardiac marker analyzer (such as troponins and BNP)

a) Structural and governance requirements (Cl. 5.0 of ISO 15189:2022)

Laboratory Director shall have the overall responsibility of Technical / Advisory / Scientific operations of the POCT coordinating committee. Such a committee should include representatives of those who use the services ((Consultants/physicians) those who deliver the services (nurses, nurse practitioners, health care providers, technical assistants) along with the representative of organization's management team. Committee is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed.

b) Resource requirements (Cl. 6.0 of ISO 15189:2022)

i. Personnel

Testing may be performed by non-laboratory personnel such as physicians, physician assistants, nurses and technical assistants, MLTs.

ii. Competence requirement

The POCT results depend heavily on robustness of device and competence of personnel. Training strategy for POCT shall include understanding the context of the test (Clinical requirement, action taken on the result provided, nature & method of the test), patient

preparation (e.g., diurnal variation, drugs), sample requirement & its collection, preparation of analytical device, performance of Quality control and test along with reporting, interpretation, documentation and health and safety issues. Competency assessment of the operators shall be periodically evaluated for assessing skills and further training requirements.

iii. Training of users

All POCT users shall receive training for the POCT device prior to authorizing the personnel to operate the POCT. Training shall be hands-on approach and must be deemed competent. Operator training is vital for quality POCT programs.

c) Equipment (Cl. 6.4 of ISO 15189:2022)

i. POCT Device

All devices (handheld and bench top) shall have the following features documented:

- Specimen type, sample preparation requirements, test menu and performance characteristics such as accuracy, precision, specificity for the analyte, turnaround time, calibration frequency, potential interferents, calibrators and reagent stability, lot-to-lot variation for reagents and calibrators, and QC requirements, Quality control and operator lockout management and data / software connectivity. It is ideal and preferable to choose a POCT device with analyte principles to be the same as the central clinical laboratory testing facility.

- Device verification for analytical performance at the Initial stage of its introduction and ongoing verification shall be done. The minimum guidelines are as follows:

	Type of device	Precision	Comparison	Linearity
Initial Device verification	Low	Both negative and positive QC to be run for 5 days	abnormal and 5 normal patient samples. Compare to central /clinical lab method	NA
	Moderate & High	Within run (Two levels of QC run a total of 5 times in one run)	20 patient samples to ensure it covers the entire range of assay measurement. Compare to central/clinical lab method	Vendor supplied linearity material to be analyzed in duplicate or series of dilution from a high patient sample and measure 3 levels in duplicate
Ongoing Device verification for additional	Low	Both negative and positive QC to be run for 1days		
	Moderate	Within run (two levels of QC run a total	5 to 10 patient samples or EQA /PT specimens	Required only if Linearity performance

devices/backup within an existing POCT program		of 5 times in one run)	comparison with central clinical lab method	was marginal during initial verification
	High	Within run (two levels of QC run a total of 5 times in one run)	10 patient samples or QC sample (that span assay measurement range) comparison with central clinical lab method	Vendor supplied linearity material to be analyzed in duplicate or series of dilution from a high patient sample and measure 3 levels in duplicate

- Intra- Instrument comparison for all types of devices should be done using PT sample or split-sample testing once per year with a minimum of two specimens including normal and abnormal specimens. Split-sample testing shall be with another accredited laboratory for POCT.
- Interlaboratory comparison of non-labile parameters shall be done with another accredited laboratory for POCT.

ii. Intra-instrument comparison:

- Within the same organization, the devices located in different areas are compared for the same analytes. Eg. device 1 glucometer located in PICU and device 2 glucometer located in MICU.
- For comparison either a whole blood sample collected from one patient can be aliquoted for testing or finger prick specimen from the same patient to be tested for glucose on both devices.
- For moderate and high complexity devices, Inter-Instrument comparison between POCT and central clinical laboratory shall be performed twice per year with a minimum of three specimens with low, medium and high concentration (six specimens in total per year).

d) Reagents and consumables (Cl. 6.6 of ISO 15189:2022)

- New lots of reagents and change in spares / consumables should be verified for precision and compared to central clinical laboratory.
- New reagent lot evaluation: Devices with low complexity shall be verified once with one QC material (each of positive and negative QC). Devices with moderate & high complexity shall be verified three times for each level of QC material.

e) Documentation of examination procedure (Cl. 7.3.6 of ISO 15189:2022)

Policies and procedures for all POCT devices shall be documented and a copy made available at all locations using the device.

f) Ensuring the validity of examination results (Cl. 7.3.7 of ISO 15189:2022)

i. Internal quality control (Cl. 7.3.7.2 of ISO 15189:2022)

One level should be performed per shift and same to be documented after verifying for acceptance. Wherever possible, for quantitative parameters, quality control ranges should be established, and variations within ± 2 SD are acceptable. Root cause analysis should be done for all QC results outside of acceptable limits and documented.

New Quality control material lot-to-lot evaluation for low complexity device shall compare one measurement with previous QC material. In the case of moderate and high complexity devices, quality control material lot-to-lot evaluation shall be done.

An infectious disease POCT for antibody shall include anti-human immunoglobulin control.

ii. External quality assessment (EQA) (Cl. 7.3.7.3 of ISO 15189:2022)

POCT devices shall be subject to minimum of two verification/comparison using EQA samples per year or with split samples when EQA is not available (with another accredited laboratory in a different organization).

g) Post-examination processes (Cl. 7.4 of ISO 15189:2022)

i. Reporting of results (Cl. 7.4.1 of ISO 15189:2022)

The result output from POCT device shall be released directly and same shall be documented. Report should include all necessary components such as patient identification, reference intervals, unit of measurement, date, time, traceable to operator performing test and release of report.

ii. Critical result reports (Cl. 7.4.1.3 of ISO 15189:2022)

POCT program shall have a procedure to notify the concerned authority of results that fall outside of critical decision limits.

h) Evaluations (Cl. 8.8 of ISO 15189:2022)

i. Quality indicators (Cl. 8.8.2 of ISO 15189:2022)

Quality of the POCT process depends on regular monitoring of quality indicators that should include but not limited to positive patient ID procedures, specimen and reagent labelling, performance of QC testing according to the procedure for the device, EQA performance and compliance with policies related to follow-up of results, such as critical results, or results above or below the assay measurement range of the POCT device.

ii. Internal audit (Cl. 8.8.3 of ISO 15189:2022)

Internal Audit shall be performed once a year per POCT program although regular audits are crucial to identify non-conformances and compliance with POCT policies and procedures. Audit should include but not limited to procedure compliance with positive patient identification, performance of QC at defined frequency, documentation of results, evidence of follow-up on results, compliance with POCT ordering procedures and documentation process, labeling and storage of reagents as required and detailed in the procedure.

Appendix A

List of Routine, Special and highly Specialized tests

(This list is not exhaustive but only indicative)

A.1 Clinical Biochemistry & Chemical Pathology:

Basic (Routine) tests:

Acid phosphatase
Alanine transaminase
Albumin
Alkaline phosphatase
Aspartate transaminase
Bilirubin (Total, direct and indirect)
Bicarbonate
Calcium (total)
Chloride
Cholesterol (total)
CK (total)
C-reactive protein (CPR)
Creatinine
CSF (Full report)
Electrolytes (Na, K and Cl)
Feces for reducing substances
Fluid – full report
Fluid- protein
Fluid- sugar
Gamma glutamyltransferase
Glucose
Iron and TIBC
HDL cholesterol
Lactate dehydrogenase
LDL cholersterol
Magnesium
Phosphate
Proteins (total)
Amylase
Troponin T-qualitative
Troponin I-qualitative
TSH (except for neonates upto 3 months)
Urea
Uric acid
Urinary amylase
Urinary (sodium &potassium)
Urinary potassium (spot urine)
Urinary sodium (spot urine)
Urine for bilirubin
Urine for glucose
Urine for ketone bodies
Urine for proteins
Urine for reducing substances
Urine for urobilinogen
Urine for β-HCG (qualitative)
Urine for dysmorphic red blood cells
Oral glucose tolerance test (OGTT)
Hydroxybutyrate dehydrogenase
Stool Fat Globules

Special Tests:

Aldolase
Ammonia
Anti-TG antibodies
Anti-TPO antibodies
Bicarbonate
Calcium (ionized)
C3 & C4
CK-MB
CRP- high sensitive
Creatinine clearance
Ferritin
Folate
Fructosamine
Glucose challenge test (GCT)
HbA_{1c}
IgG
IgM
IgA
Ketone bodies in plasma
Lactate
Lipase
Lithium
Myoglobin
Osmolality serum
Oestradiol
Stone analysis
Tacrolimus
Triglycerides
Transferrin
T4- free
T3- free
TSH
Urinary albumin/creatinine ratio
Urinary amylase
Urinary Calcium (24 hour excretion)
Urinary Calcium (spot urine)
Urinary Calcium excretion studies
Urinary Copper (24 excretion)
Haptoglobin
Urinary micro-albumin/creatinine ratio
Urinary myoglobin
Urinary osmolality
Urinary phosphate (24 hour excretion)
Urinary phosphate (spot urine)
Urinary protein/creatinine ratio (spot urine)
Urinary protein (24 hour excretion)
Urine for Bence Jones proteins
Urinary potassium (24 hour excretion)
Urinary potassium (spot urine)
Urinary Calcium/creatinine ratio (24 hour excretion)
Urinary porphyrins
Urine for Gravindex dilution
Urinary oxalate (24 hour excretion)
Urinary sodium (24 hour excretion)
Urinary sodium (spot urine)
Urinary uric acid (24 hour excretion)
Vitamin B_{12}
Zinc

Highly Specialized Tests:

1. General Biochemistry

Amino acids (serum and urinary)
Amylase (Pancreatic)
Apolipoprotein A-1
Apolipoprotein B
d- dimer
BNP
β2-microglobulin
β carotene
Homocysteine
IgE total
C1esterase inhibitor
Cyclosporin
Ceruloplasmin
Cholinesterase
Copper
Cryoglobulin
Cystatin C
Lactate
Lead
Lipoprotein (a)
Methotrexate
NGAL
Protein electrophoresis (serum)
Protein electrophoresis (urine, CSF)
Immunofixation
Sd-LDL
Troponin I quantitative
Urinary β2-microglobulin
α1 - antitrypsin
Tacrolimus
Toxicology profile- identified
Toxicology profile- unidentified
Immunoglobulin profile
Ceruloplasmin

2. Endocrine tests

1,25 $(OH)_2$ cholecaiciferol
17-OH progesterone
25 (OH) cholecalciferol
ACTH
Aldosterone
Androstenedione
Anti-TSH receptor antibody
Beta-crosslaps
Calcitonin
Catecholamines -
(Epinephrine and norepinephrine in plasma and urine)
Cortisol
C-peptide
Dehydroepiandrosterone sulphate (DHEAS)
Urinary free cortisol (24 hour)
Dehyroepiandrosterone
Erythropoeitin
FSH
GH
Insulin
Insulin-like growth factors (IGF -1, IGF-11)
LH
Metanephrines (metanephrine and normetanephrine) in serum
Metanephrines (metanephrine and normetanephrin) in urine
Oestrogen
Osteocalcin
P1NP
Parathyroid hormone (PTH)
Plasma rennin activity (PRA)
Chromagrannin
Prolactin
Testosterone
TSH (Up to 3 months) Urinary free cortisol (24 hour)
T3 (free and total)
T_4 (free and total)
T_4 (Up to 3 months)
Urinary HIAC
Progesterone
Urinary VMA
SHBG

3. Tumor Markers

CA 125
CA 15-3
Ca 19.9
Carcinoembryonic antigen (CEA)
NSE
β-HCG
PSA (free)
Prostatic Specific Antigen (PSA)
Thyroglobulin
S-100
Alpha Feto Protein (AFP)

4. Therapeutic Drug Monitoring

Carbamazepine
Digoxin
Gentamycin
PCM
Phonobarbitone
Phenytoin
Theophyllin
Valproic acid
Cyclosporine
Tacrolimus
Sirolimus

5. Drugs of Abuse testing

Amphetamines/Ecstacy
Barbiturates
Benzodiazepines
Coccaine
EDDP
Methadone
Opiates
THC
Ethanol

6. Very Highly Specialized Tests (Dynamic Function Tests)

GH Stimulation
Short Synacthen & Long Synacthen
Overnight dexamethasone suppression test
Low dose dexamethasone suppression test
Prolonged dexamethasone suppression test
Glucagon stimulation test
Excise stimulation test
Macro-prolactin
Special procedures such as Endocrinology investigations in in-vitro fertilization
Venous sampling including Adrenal vein sampling, Pituitary vein sampling and venous sampling for pancreatic tumour

A.2 Haematology:

Basic (Routine) tests:

- Full blood count including differential count and platelet count
- Erythrocyte Sedimentation Rate (ESR)
- Packed cell volume
- Reticulocyte count
- Prothrombin time
- Activated partial thromboplastin times (APTT)
- Thrombin time
- Bleeding time
- Clotting time
- Plasma Haemoglobin
- Blood group
- Brewers test
- Fibrinogen
- D Dimer
- FDP
- Malaria parasites
- Rh tube method and direct coombs test with polyspecific antisera
- Blood film for malaria and microfilaria

Special Tests:

- Blood Pictures
- Red cell inclusions: HbH, Heinz bodies etc.
- Osmotic fragility test
- Sickling test
- Cryo-haemolysis
- Inhibitor screening
- Clot solubility test
- Lupus anticoagulant
- KCT
- Thrombophilia screen – Protein C, Protein S, Anti Thrombin III, aPCR etc.
- ROTEM/Thromboelastography
- NAP score
- Plasma Heamoglobin , Methaemoglobin, Meth heam albumin, cryoglobin in plasma
- Urine hemoglobin by hand or spectroscopy
- Euglobin clot lysis time
- Urine haemosiderin, Urine dysmorphic red cells
- Ham Test, sucrose lysis
- Screening for spherocytosis, osmotic fragility test and cryohaemolysis
- Direct coombs test with monospecific antisera and indirect coombs test
- Screening for G6PD deficiency
- Acid elution test, Kleihauer test, HbH detection
- LE cells
- ANA and Ds-DNA detection, rheumatoid factor
- Perl stain for blood and bone marrow films
- Cytochemical staining on blood and bone marrow films

- Coagulation tests –clot solubility test, factor correction, inhibitor detection,
- Factor assay (f VIII, f IX Etc) activity and quantity, Fibrinogen assay
- Anticardiolipin antibodies
- Sickle solubility test,
- Lupus antibodies (DRVVT), KCT
- Coagulation based tests for hereditary thrombophilia
- Platelet function tests by agrigometry
- Tests for von Willebrand disease
- Red cell enzyme assays

Highly Specialized Tests:

- Bone marrow aspiration and trephine biopsy
- Reticulin stain
- Cytochemistry on Peripheral blood or bone marrow: Perl stain, Sudan black Stain, PAS stain, Dual esterase etc.
- Immunohistochemistry on trephine biopsy: CD20, CD3 etc.
- High performance liquid chromatography
- Haemoglobin electrophoresis
- Capillary electrophoresis
- Flow cytometry
- Platelet function test (Platelet aggregometry)
- Clotting Factor assay
- Inhibitor assay
- Anti Xa assay
- HIT screen
- Urine haemosiderin
- HAM test
- quantification (Hb) HPLC
- Electron microscopy for haemotological disorders
- SDS PAGE (Polyacrylamide Gel Electrophorosis)
- Molecular Genetics (RFLP , PCR and sequencing)
- Cytogenetics studies
- FISH technique
- Bone marrow transplantation related investigations
- Immuno-histochemical staining of bone marrow specimens
- Soluble transferring receptor level

A.3 Microbiology:

Basic (Routine) Tests:

- Blood – malaria parasites
- Stools – Direct smear/AOC

Special tests:

- Tuberculosis: Direct smear for AFB
- Leprosy: Modified ZN stain for nasal discharge/biopsy
- Direct Microscopy of CSF
- Gram stain- HVS, diagnose STI, CSF
- CSF bacterial antigen test
- Cryptococcal antigen test
- Microscopic evaluation of direct wet-mount preparation in bacteriology other than tests listed under basic tests
- Microscopic evaluation of direct wet-mounts for presence or absence of parasites other than tests listed under basic tests
- Dark field examination for *Treponema pallidum*
- Bacterial culture and ABST
- Isolation of yeast from high vaginal swabs with identification limited to *Candida albicans*
- Vaginal swabs: Trichomonas
- Scraping of skin/nails/hair for microscopy (for mycology)
- India ink staining of CSF
- Strip tests and Immuno-chromatography, tests for diagnosing or detecting immunity to infection
- ELISA, RPHA, PHA,HI, Immunodiffusion tests, Immuno-chromatography, Particle and latex agglutination for diagnosing or detecting immunity to infection except those listed in highly specialized tests
- Blood- concentration test for microfilaria
- Stools- concentration test for parasites
- Fi larial FAT, special staining for Cryptosporidium
- Automated procedures that do not require operator intervention during the analytical process but require clinical validation
- Biological test for autoclave efficacy

Highly specialized tests:

- Bacterial antigen or toxin, viral antigen test procedures or kits requiring microscopic evaluation (eg. VDRL)
- Special techniques for antigen/antibody detection eg. – IF, Chemiluminence etc.
- Bacterial typing
- *Brucella, Campylobacter* and other fastidious bacterial cultures
- *Leptospira* MAT and culture
- Molecular diagnostic assays
- MIC assays
- Antimicrobial assays
- Tuberculosis: Sputum and other body fluids for TB culture, identification and drug sensitivity
- Sexually transmitted infections: culture and serology other than tests mentioned under special tests category
- HIV testing (Western blot test)
- Direct smear for Negri bodies
- Direct Fluorescent test (FAT) for Rabies antigen
- Rabies Antibody Test- RFFIT
- Virus isolation, identification and typing
- Automated or semi-automated procedures in bacteriology requiring operator intervention during the analytic process
- Pus and body fluids for amoeba culture and stools for amoeba culture, tape worm segments and worm egg counts
- Special tests for toxoplasmosis and leishmaniasis
- All parasitic cultures
- Direct microscopy for fungi of all samples excluding skin, nails and hair
- Special staining for fungi
- Fungal culture and Antifungal susceptibility testing
- ELISA tests for mycology
- Tests to detect fungal toxins
- Therapeutic drug level monitoring for anti-fungal drugs
- Disinfectant testing
- Vaccine Quality testing

Immunology- Highly specialized tests:

- Allergen specific IgE (ELISA/ImmunoCap)
- ELISA for total IgE
- ELISA/RID/turbidometry for serum Immunoglobulin (IgG, IgA,IgM)
- Indirect Immunofluorescence testing for autoimmunity (Antinuclear antibody, antimitochondrial antibody, anti DS DNA antibody, anti smooth muscle, anti LKM, anti neutrophil cytoplasmic (ANCA) etc.)
- Direct immunofluorescence for bullous disease, and glomerulonephritides
- T cell function assay
- Flowcytometry
- ELISA for autoimmue testing (anti cardiolipin, anti phospholid, anti thyroglobulin, anti β 2 glycopritein1, Anti neutrophil cytoplasmic antibody (ANCA), anti extractable nuclear antigen ENA, etc)
- Nitro blue tetrazolium assay

A.4 Histopathology:

Highly Specialized Tests:

- Fine needle aspiration cytology
- Cytopathology of aspiration and non aspiration fluids and exfoliated fluids and imprint cytology
- Cervical pap cytology
- Immuno fluorescence microscopy
- Electron microscopy
- Frozen section biopsy

A.5 Immunology:

- All the tests are highly specialized tests

A.6 Molecular Biology:

- All the tests are highly specialized tests

A.7 Pharmacology:

- All the tests are highly specialized tests

A.8 Nuclear Medicine (in-vitro tests):

- All the tests are highly specialized tests

A.9 Andrology:

Routine Tests:
Seminal Fluid Analysis (SFA)

Special Tests:
Sperm processing for Intra Uterine Insemination (IUI)
Sperm Freezing

A.10 Embryology:

Highly Specialized Tests:
In vitro Fertilization Techniques
Embryo Freezing

COMPOSITION OF THE TECHNICAL ADVISORY COMMITTEE

1	Dr (Ms) Rajitha Samarasinghe Consultant Clinical Pathologist, Apeksha Hospital, Maharagama	Chairperson
2	Prof. K A C Wickremaratne Professor in Haematology, Department of Pathology, Faculty of Medicine, University of Ruhuna	Member
3	Dr (Ms) Sriyani Nanayakkara Consultant Histopathologist, Eye Hospital, Colombo.	Member
5	Dr (Ms) Sujatha Pathirage Consultant Microbiologist, Medical Research Institute, Dr. Danister De Silva Mawatha, Colombo 08.	Member
6	Dr (Ms) J I Abeynayake Consultant Virologist, Medical Research Institute, Dr. Danister De Silva Mawatha, Colombo 08.	Member
7	Prof. (Ms.) A Manamperi Senior Lecturer, Head Molecular Medicine Unit, Faculty of Medicine, University of Kelaniya	Member
8	Ms Mithila Gunasekara Deputy Director Sri Lanka Accreditation Board	Member
9	Ms Shashini Ishara Assistant Director, Sri Lanka Accreditation Board	Secretary