



**SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT**

SPECIFIC CRITERIA FOR
MEDICAL/CLINICAL TESTING LABORATORIES

ABBREVIATIONS

AEA	-	Atomic Energy Authority
APLAC	-	Asia Pacific Laboratory Accreditation Cooperation
AS	-	Australian Standards
ASTM	-	American Society for Testing & Materials
BOD	-	Biological Oxygen Demand
BRI	-	Biological Reference Interval
CBC	-	Complete Blood Count
CDDA	-	Cosmetics, Drugs and Devices Authority
CSF	-	Cerebrospinal Fluid
CV	-	Coefficient of Variation
DNA	-	Deoxyribo Nucliec Acid
EDTA Acid	-	Ethylene Diamine Tetra Acetic Acid
ELISA	-	Enzyme Linked Immunosorbent Assay
EM	-	Electron Microscopy
EQAS	-	External Quality Assessment Scheme
FNA	-	Fine Needle Aspiration
FNAC	-	Fine Needle Aspiration Cytology
h	-	Hour(s)
HBV	-	Hepatitis B Virus
HIV	-	Human Immunodeficiency Virus
HLA	-	Human Leukocyte Antigen
HPLC	-	High Performance Liquid Chromatography
IFCC	-	International Federation of Clinical Chemistry and Laboratory Medicine
INR	-	International Normalized Ratio
ISO	-	International Organization for Standardization
MUSSD	-	Measurement Units, Standards and Services Department
MNPT	-	Mean Normal Prothrombin Time
MRA	-	Mutual Recognition Arrangement
PCR	-	Polymerase Chain Reaction
QC	-	Quality Control
RNA	-	Ribo Nucleic Acid
WHO	-	World Health Organization

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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 15189:2007 *Medical Laboratories- 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.

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2. SCOPE OF ACCREDITATION

The scope of the accreditation is applicable to the following medical laboratory services:
(2.1 to 2.9)

- 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 histopathological and cytopathological examination of biopsy material and Immuno Histochemistry.
- 2.7. **Immunology:** Service includes the investigation of immuno deficiency and allergy.
- 2.8. **Molecular Biology:** Molecular biological techniques used in the diagnosis of infective, genetic and other disorders.
- 2.9. **Pharmacology:** Service includes Therapeutic Drug Monitoring, Toxicological Investigations and Drugs of Abuse.
- 3.0. **Nuclear Medicine:** Immunological Techniques for hormone assays and Tumor markers detected by radioisotopes.
- 3.1. **Andrology:** Service includes Seminal Fluid Analysis (SFA), Sperm processing for Intra Uterine Insemination (IUI) and Sperm Freezing.
- 3.2. **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. A representative sample of these facilities shall be assessed by SLAB for their compliance with the requirements.

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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. Following classification shall be used for administration of the accreditation scheme and for determining fee structure:

Small Laboratory: A laboratory receiving < 50 Test Requests* per day

Medium Laboratory: A laboratory receiving 51- 400 Test Requests* per day

Large Laboratory: A laboratory receiving > 400 Test Requests* per day

* **Test Request:** One test or a combination of tests of which results can be obtained by applying one test procedure / methodology in a given field of testing.

4. MANAGEMENT REQUIREMENTS (ISO 15189: Clause 4)

4.1 ORGANIZATION AND MANAGEMENT (ISO 15189: Clause 4.1)

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.

4.2 EXAMINATION BY REFERRAL LABORATORIES (ISO 15189: Clause 4.5)

Laboratory shall have documented policy and procedure for selecting and referring tests to other laboratories and referring for second opinion to consultants. The accredited tests can be referred only to a laboratory accredited by SLAB or its MRA partner. In the test report the accredited laboratory shall specify the name of referral laboratory and identify the tests performed and the results obtained by such referral laboratory.

4.3 EXTERNAL SERVICES AND SUPPLIES (ISO 15189: Clause 4.6)

Each lot of reagents shall be checked against earlier tested in-use reagent lots or with a suitable reference material before being placed in service. The results should be recorded. Each lot of antibiotic sensitivity discs shall be checked for activity/ potency before being placed in service.

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4.4 CONTINUAL IMPROVEMENT (ISO 15189: Clause 4.12)

The laboratory must have a comprehensive program for Quality Improvement, which shall incorporate salient quality indicators for monitoring laboratory's performance. This shall describe the evaluation of various aspects such as, but not limited to, the following

- sample collection and identification
- transportation and processing
- analysis and reporting of results
- turnaround time
- complaints
- equipment downtime
- uncertainty of measurements (monthly % CV)
- performance in EQAS

4.5 QUALITY AND TECHNICAL RECORDS (ISO 15189: Clause 4.13)

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:

Particle Cell counter data	– one week
Molecular diagnostic gel pictures	– 05 years
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

Minimum period for retention of test reports:

Histopathology, Cytopathology, Molecular Biology	- 05 years
Bone Marrow reports	- 05 years
Blood Pictures	- 06 Months
Other disciplines	- 1 year

5. TECHNICAL REQUIREMENTS (ISO 15189: Clause 5)

5.1 PERSONNEL (ISO 15189: Clause 5.1)

The Director, persons authorized to review and release the results, and Laboratory Staff 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.

5.1.1 *Qualification norms for Director/ Chairman/ Head (howsoever named).*

Qualifications	Experience	Other Requirements
Basic Medical / Science based Degree with Management Experience or Diploma in Medical Laboratory Technology or other equivalent qualification*	2 years (Technical and Management)	Experience in Laboratory Administration and Consultative and Advisory Services

* Basic qualifications could be decided by the Management subject to justification.

5.1.2 *Qualification norms for Persons authorized to review and release the results or authorized signatories are listed below.*

(Refer Appendix A for a listing of Highly Specialized, Special and Routine tests under each field of 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)/ Equivalent Qualifications <i>or</i> PhD with experience in Clinical Biochemistry	None 01 year post qualification experience	Demonstrate knowledge and competence in Clinical Biochemistry, Clinical Endocrinology and Biochemical Tumor Markers.
Special Tests	As above <i>or</i> MBBS with Diploma in Pathology or Chemical pathology <i>or</i> BSc / MSc degree in Clinical Laboratory Sciences (with Biochemistry as a subject) <i>or</i> BSc in Chemistry with MSc in Clinical Chemistry or Analytical Chemistry	06 months post qualification experience in the relevant field (Note 1) 06 months experience in a Chemical Pathology Laboratory (Note 1) 06 months experience in a Chemical Pathology Laboratory (Note 1)	(Note 2) (Note 2)
Routine Tests	As above <i>or</i> M.B.B.S <i>or</i> BSc / MSc degree in Clinical Laboratory Sciences (with Biochemistry as a subject) <i>or</i> BSc in Chemistry with MSc in Clinical Chemistry or Analytical Chemistry <i>or</i> Diploma/Certificate in Medical Laboratory Technology or equivalent training <i>or</i> A/L 3 subjects with chemistry as one subject and 3 years on the job training in laboratory testing in the specific area	Six (06) months experience in Laboratory Medicine (Note 1) 03 Months experience in a Chemical Pathology laboratory (Note 1) 03 months experience in a Chemical Pathology Laboratory (Note 1) One year experience in a laboratory (Note 1) Minimum of 3 years on the job training	(Note 2) (Note 2) (Note 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. Performing tests and release of results under the supervision of a Pathologist/Head of the Laboratory or designee.

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.*

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Haematology and Immunohaematology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	M.B.B.S with M.D. (Haematology) <i>or</i> Equivalent Qualification <i>or</i> PhD in Haematology	None 01 year post qualification experience	Demonstrate knowledge and high competence Clinical & Technical Experience
Special Tests	As above <i>or</i> MBBS with Diploma in Pathology <i>or</i> 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 2) (Note 2)
Routine Tests	As above <i>or</i> M.B.B.S <i>or</i> BSc / MSc degree in Clinical Laboratory Sciences <i>or</i> Diploma/Certificate in Medical Laboratory Technology or equivalent training <i>or</i> A/L 3 subjects with chemistry or Biology as one subject and 3 years on the job training in laboratory testing in the specific area	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) Minimum of 3 years on the job training	(Note 2) (Note 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. Performing tests and release of results under the supervision of a Pathologist/Head of the Laboratory or designee.

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.*

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Microbiology and Serology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	M.B.B.S with M.D. (Medical Microbiology, Virology or Parasitology as relevant) <i>or</i> Equivalent Qualification <i>or</i> PhD in Clinical/Medical Microbiology covering the relevant discipline.	None 1 year post qualification experience	Demonstrate knowledge and high competence Clinical and Technical Experience (Note 2)
Special Tests	As above <i>or</i> MBBS with Diploma in Microbiology <i>or</i> MSc. in Medical/Clinical Microbiology <i>or</i> BSc/MSc degree in Clinical Laboratory Science	06 months post qualification experience in the relevant field (Note 1) 06 months experience in the relevant field (Note 1) 1 year experience in the relevant field (Note 1)	(Note 2) (Note 2) (Note 2)
Routine Tests	As above <i>or</i> M.B.B. S <i>or</i> BSc / MSc degree in Clinical Laboratory Sciences <i>or</i> Diploma/Certificate in Medical Laboratory Technology or equivalent training <i>or</i> A/L 3 subjects with Biology as one subject and 3 years on the job training in laboratory testing in the specific area	06 months experience in Laboratory Medicine One year experience in a laboratory (Note 1) One year experience in a laboratory (Note 1) Minimum of 3 years on the job training	Release of results under the supervision of Microbiologist/Head of the Laboratory or designee (Note 2) Release of results under the supervision of Microbiologist/Head of the Laboratory or designee (Note 2) Release of results under the supervision of Microbiologist/Head of the Laboratory or designee Performing tests and release of results under the supervision of Microbiologist/Head of the Laboratory or designee.

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) <i>or</i> Equivalent Qualification		Demonstrate knowledge and high competence Clinical and Technical Experience
Special Tests	As above	As above	Demonstrate knowledge and high competence
Routine Tests	As above Cyto Screeners: Diploma/Certificate in Medical Laboratory Technology or equivalent technician training	As above screeners training	Demonstrate knowledge and high competence Negative Pap Smear in the screening programme can be signed by a Cyto screener under the supervision of pathologist on periodic basis

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

Immunology

Test Classification	Qualifications	Experience	Other requirements/Remarks
Highly Specialized Tests	PhD in Clinical Immunology M.B.B.S and M.D. in Chemical Pathology / Haematology/ Microbiology with experience in Clinical/Laboratory immunology	2 years	Demonstrate knowledge and high competence Clinical and Technical Experience
Special Tests	As above <i>or</i> MBBS with Diploma in Pathology <i>or</i> BSc / MSc degree in Clinical Laboratory Sciences	1 year post qualification experience in the relevant field 3 years experience in the relevant field	

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

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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	2 years	Demonstrate knowledge and high competence in Molecular Biological Diagnostic Techniques Clinical and Technical Experience
	or BSc / MSc degree in Clinical Laboratory Sciences	2 years	

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

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5.1.3 Qualification norms for Laboratory Staff assigned to perform sampling, examinations (tests), Operate test equipment and Laboratory support functions.

Test Classification	Qualifications (minimum)	Experience	Remarks
Performance of Highly Specialized Tests	Decided by the Management/Consultant based on nature and complexity of tests		Certain tests as decided by the management shall be performed by the persons having qualifications as specified in 5.1.2
Performance of Special Tests	Diploma/Certificate in Medical Laboratory Technology or A/L 03 subjects with Chemistry and/or Biology as one subject (Notes 1 & 2)	06 months One year training	
Performance of Routine Tests	Diploma/Certificate in Medical Laboratory Technology or A/L 03 subjects with Chemistry and /or Biology as one subject (Notes 1 & 2)	06 months One year training	
Phlebotomist	O/L/ with adequate training	1 year	
Nurses	O/L/ with adequate training	1 year	
Support Staff	Minimum Grade 8	1 year	

Note 1: *If persons with lower educational qualifications are assigned to perform routine tests, the management should ensure that adequate training and supervision is provided in the performance of test.*

Note 2: *The laboratory shall have a system for providing necessary training to technical staff in the operation of new analytical equipment and/ or performance of new tests before he/ she is assigned such work.*

5.1 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

(ISO 15189: Clause 5.2)

Towards effectiveness of operations, the laboratory shall ensure adequate space in relation to the following:

- Patient reception
- Sample collection
- Workbench
- Equipment
- Storage of volatile and inflammable reagents
- Radioisotope related work as per the regulatory agency (AEA) requirement
- Washing and Decontamination
- Isolation for biohazardous materials
- Fire safety
- Waste Disposal

The laboratory should have adequate lighting, power plugs and uninterrupted power supply. The use of exposed cables should be minimum.

The laboratory shall ensure that adequate electrical service is available so that there is no interruption in power supply that may lead to compromise of stored data. All computers, peripherals, equipments and communication devices should be supported in such a way that service is not likely to be interrupted. The laboratory shall have procedures in place to ensure the integrity of refrigerated and/or frozen stored samples/reagents/consumables in the event of an electrical failure and emergency exist.

The accommodation and environmental conditions are also applicable to primary sample collection facilities at sites other than the permanent laboratory facility.

5.2.1 Haematology:

Specimen Collection area – This could be a separate room or area with adequate lighting.

Procedure room - for Bone Marrow Aspiration Biopsy with adequate ventilation, bed, working bench to prepare slide, store area for sterile material and needles, sink with running water, patients waiting area, disposal of material (cotton wool/ gauze).

Clinic – Separate Clinic area (if a clinic functions) with adequate space for patient's waiting area, Blood collection area and Doctors area. Good ventilation, Light, adequate space, working benches.

Main Lab – Separate area for Blood analyzer machines for Serology testing and special Haematology staining with good ventilation, light and space, First Aid Box. All laboratories must have a fire escape. Space for storage of glass slides, stationary, microscopes, reagents.

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5.2.2 Microbiology:

Sample processing area, media room and waste disposal must conform to the guidelines prepared by the authorities (Sri Lanka College of Microbiologists) and regulations enforced by the Central Environmental Authority as appropriate.

5.2.3 Histopathology:

Specimen Collection area – This could be a room or a area (or this could also be in the cutup room or in the main lab)

Tissue cut up room- It has to be separated from the rest of the lab – adequate ventilation; large windows with fans to take away the formalin vapor.; sink with tap water, tables, cupboards to keep the sample bottles. Proper disposal of unwanted samples and tissues (garbage bags, tins) Disposal of tissues is another important issue but varies in different setups (incinerators are available only in some institutions only).

Main lab – Good ventilation and light, (air condition, if possible); enough space for workbench and equipment including a fridge. tap water sink. Space for proper storage of chemicals, first aid box, equipment; the specimen collecting area may be part of this lab or can be separated if there is additional area. Space for storage of used paraffin blocks and slides. The cupboards for this purpose can be kept either in the lab or in another area if available. Fire equipment also should be kept in the same laboratory as well.

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.

The electron microscopy room shall have:

- i. facilities in place for temperature control and chilled water supply
- ii. insulated cabling kept away from the work areas
- iii. proper seating available to allow for optimal ergonomic positioning of the person using the microscope
- iv. dark room with adequate ventilation.
- v. warning light on the door of the dark room indicating usage.

5.2.4 Cytopathology:

An examination bed with screen in a room or in an area which has privacy for FNAC procedure. The laboratory should have good light, table to keep the bottles and other equipment, gloves etc.

5.2.5 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

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5.2.6 Pharmacology:

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

5.2.7 Nuclear Medicine:

The Laboratory shall follow Radio Isotopic Requirements of AEA

5.3 LABORATORY EQUIPMENT (ISO 15189:Clause 5.3)

5.3.1 General

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 adequate 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.

A documented programme 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.

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 autoanalyzers, automated coagulometers and ELISA readers etc., shall be calibrated at least once a year.

Many types of equipment may be calibrated in-house by using reference materials or comparative techniques. In such cases, reference materials should demonstrate traceability to SI units or the appropriate measurement standards.

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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.

(Reference: Dacie and Lewis, 2001. In Practical Haematology 9th edition, published by Churchill Livingstone, p 571)

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.

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.,

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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	Every six months (where operating speed is specified)	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
Masses	One year	ASTM E617
Piston-operated volumetric apparatus pipettes and dispensers.	Initial and every six months	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

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 Commercially prepared Controls and every time the reagents are being changed. Daily in house controls.
Chemical 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. Daily in house controls
Bone Marrow+ Trepine 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 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	Absorbance checks
PCR Machines	One year	

* 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 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.

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5.3.2 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)

5.3.3 Histopathology:

Tissue Processing

- a. Depending on the workload the laboratory shall develop a procedure to change the tissue processing fluids and maintain a record of it.
- 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.

Microtome

- a. The setting of the microtome indicating the thickness of sections shall be checked before use.
- b. Microtome with non-disposable knife shall have a safety shield.

Slide warming stage

- a. Temperature of slide warming stage shall be checked weekly

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Flotation bath

- a. The fluid in the flotation bath shall be changed at least once a day.
- b. The surface of the water bath shall be skimmed regularly during section cutting to remove floaters.
- v) *Frozen section Microtome*
 - a. Kept in a safe area as aerosols, infective material can be spread.

Cryostat

- a. Has to be calibrated and the temperature has to be set daily.

5.3.4 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 on CSF must use cytocentrifuge for processing the samples.

5.3.5 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.

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5.3.6 Immunology:

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

5.4 PRE-EXAMINATION PROCEDURES (ISO 15189: Clause 5.4)

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

5.4.1 Haematology:

For the tests for monitoring anticoagulant therapy the request forms must have a column for the physician ordering the test to indicate the purpose of the test e.g. monitoring heparin/ low molecular weight heparin and/or oral anticoagulant therapy as applicable. Also to include the time and the place from where the sample is obtained.

Indwelling Lines or Catheters:

Phlebotomists drawing blood from indwelling (arterial, central venous) or umbilical lines should have thorough training. While drawing blood from indwelling lines or catheters errors due to dilution and or contamination from flushing solution should be avoided.

When an intravenous solution is being administered in a patient's arm, blood should be drawn from the opposite arm. If an intravenous infusion is running in both arms, samples may be drawn after the intravenous infusion is turned off for at least two minutes before venipuncture and applying the tourniquet below the intravenous infusion site.

Relevant clinical data are necessary for most specialized tests. Request forms should be designed so that the requesting physician provides this information.

Blood specimens for coagulation tests should be collected in 3.2% buffered sodium citrate and Blood specimens for Full Blood Counts in EDTA Solution.

There must be guidelines for rejection of samples especially for under- or over- filled collection tubes for coagulation tests. Reasons for rejection of sample must be stated or communicated in writing to the nursing staff/ physician/ laboratory personnel responsible for sample collection.

The Sample collection Procedures and transport must conform to guidelines prepared by authorities (Sri Lanka College of Haematologists, WHO) and should be available with the Laboratory).

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5.4.2 Microbiology:

Specimens for culture and sensitivity must be processed immediately after collection. In case of delay in processing the specimen may be stored in refrigerator except CSF and anaerobic culture. In situations where the sample has to be transported it must be collected in an appropriate transport medium.

5.4.3 Histopathology:

Specimen should be properly & adequately fixed in formol saline (10%) and the formol saline volume should be 10 times more than the specimen.

For renal, and testicular Biopsy, a different fixative may be used and it has to be stated.

Frozen sections – Prior arrangements with the laboratory is mandatory. Specimen should reach the lab with in 5-10 mins. 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) shall be labelled and identified.

5.4.4 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 the Pathologist. In the absence of a Pathologist, a clinician/radiologist 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 and clinical findings with provisional diagnosis
 - c. Anatomical site of collected specimen
 - d. Date and time of specimen collection
 - e. Information regarding previous cytology report

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- 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°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.

5.4.5 Storage period of examined specimen

All the samples should be retained until the reports are received by the physician. 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°C

Special Biochemical, Endocrine and Tumor Marker tests – 3 months at -20°C

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Haematology:

Complete Blood Counts: 24 hours at 2-8⁰C

Coagulation screening test – 6-8 hours at 2-8⁰C

Haemoglobin electrophoresis and HPLC – 1 week at 2-8⁰C or longer below -20⁰C

Bone Marrow slides – 5 years *

HLA typing cell preparation – 3 days

Serology:

Three days at 2-8⁰C

Histopathology:

Specimens – 15 days

Slides/ Blocks – 5 years*

Bone marrow aspirate and corresponding blood film and biopsy – 5 years

Cytopathology:

Fluids – 24 hours at 2-8⁰C

Slides – 5 years*

Molecular Biology:

Blood samples for karyotyping – 6 days at 2-8⁰C

Extracted DNA – 5 years at -20⁰C

Extracted RNA – 5 years at -70⁰C

Molecular diagnostic gel pictures – 5 years

Flow Cytometry:

Follow the instructions of the method.

* 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.

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5.5 EXAMINATION PROCEDURES (ISO 15189: Clause 5.5)

5.5.1 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.

5.5.2 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.

5.5.3 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 -20⁰C for up to 2 weeks or at -70⁰C 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.

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5.5.4 Microbiology:

The methods recommended by college of Microbiologists, Sri Lanka and WHO.

5.5.5 Histopathology:

- i) Follow Standard Histopathology Text Books/ WHO Recommended Methods.
- ii) Staining

If any alternative type of alcohol is used it has to be properly validated.

Highly infective material ex. Prion Disease has to be handled according to WHO recommendations

5.5.6 Nuclear Medicine:

The Laboratory shall follow Guidelines prepared by AEA.

5.6 ASSURING QUALITY OF EXAMINATION PROCEDURES (ISO 15189: Clause 5.6)

5.6.1 The laboratory shall design and implement internal quality control systems that verify the attainment of the intended quality of results.

5.6.2 The Laboratory shall participate in interlaboratory comparisons provided through external quality assessment schemes.

5.6.3 Whenever formal interlaboratory comparison programmes are not available, the laboratory shall adopt mechanisms to determine the acceptability of procedures not otherwise evaluated.

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

5.6.5 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 National Guidelines/Quality Assurance published by the College of Pathologists, Sri Lanka.

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5.7 REPORTING RESULTS (ISO 15189: Clause 5.8)

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.

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.

5.7.1 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/arithmetic mean of prothrombin time of 20 normal healthy individuals) should be determined for every new lot of reagent, type of reagent and the instrument used. The INR must be appropriately adjusted for every new lot of prothrombin time reagent, types of reagent and the instrument used. Biological Reference Intervals show significant differences with each lot of reagent, 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.

5.7.2 Histopathology:

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, nature of lesion 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 a pathologist before authorizing and issuing printed or electronic reports.

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5. The turn around time for issue of reports should be 07 days but for larger specimens & tissues which need special examinations the turn around time varies (10-14 days). Histochemical & Immunochemical specimens the time period is 7-12 weeks. But for very urgent cases the report shall be made available within 03 days. In case any special procedures are carried out to further characterize the pathology, a interim report should be issued to facilitate immediate management of the patient. Final report should be issued after carrying out the special procedures in a reasonable amount of time depending upon the degree of specialization and consultancy needed.

6. 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.

5.7.3 Cytopathology:

1. A pathologist shall review and sign all reports 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. All malignancies or suspected malignancies shall be reported immediately in writing.
5. For intra-operative cytology, the smears will be stained and interpreted within 30 minutes and the result immediately communicated to the surgeon.
6. In case of reports with abnormal cytologic findings, the pathologist should make recommendations regarding further clinical/histological evaluation, where relevant.

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Appendix A

List of Routine, Special and highly Specialized tests
(This list is not exhaustive but only indicative)

A.1 Clinical Biochemistry & Chemical Pathology:

Routine tests:

Alanine transaminase	Lactate dehydrogenase
Albumin	Proteins (total)
Alkaline phosphatase	Amylase
Aspartate transaminase	Urea
Bilirubin (direct and indirect)	Uric acid
Bilirubin (total)	Urinary amylase
Calcium (total)	Urinary (sodium & potassium)
Chloride	Urinary potassium (spot urine)
Cholesterol (total)	Urinary sodium (spot urine)
CK (total)	Urine for Bence Jones proteins
Creatinine	Urine for bilirubin
Fluid – full report	Urine for glucose
Fluid- protein	Urine for ketone bodies
Fluid- sugar	Urine for proteins
Gamma glutamyltransferase	Urine for reducing substances
Glucose	Urine for urobilinogen
Hydroxybutyrate dehydrogenase	Urine for β -HCG
	Urine for dysmorphic red blood cells

Special Tests:

Acid phosphatase	LDL cholesterol
Aldolase	Lipase
Amylase (Pancreatic)	Lithium
Bicarbonate	Magnesium
C-reactive protein (CPR)	Myoglobin
Calcium (ionized)	Oral glucose tolerance test (OGTT)
CK-MB	Phosphate
Creatinine clearance	Serum osmolality
Cryoglobulin	Stone analysis
CSF (full report)	Triglycerides
Ferritin	Troponin I
Folate	Troponin T
ructosamine	Urinary albumin/creatinine ratio
Glucose challenge test (GCT)	Urinary Calcium (24 hour excretion)
Haptoglobin	Urinary Calcium (spot urine)
HbA _{1c}	Urinary Copper (24 excretion)
HDL cholesterol	Urinary micro-albumin/creatinine ratio
Iron	Urinary myoglobin
Ketone bodies in plasma	Urinary osmolality

Urinary phosphate (24 hour excretion)
 Urinary Phosphate (spot urine)
 Urinary protein (24 hour excretion)
 Urinary potassium (24 hour excretion)
 Urinary porphyrins

Urinary protein/creatinine ratio
 Urinary sodium (24 hour excretion)
 Urinary uric acid (24 hour excretion)
 Urine for Gravindex dilution
 Vitamin B₁₂

Highly Specialized Tests:

Amino acids (serum and urinary)
 Ammonia
 Apolipoprotein A-1
 Apolipoprotein B
 BNP
 β₂-microglobulin
 β carotene
 Homocysteine
 C₁esterase inhibitor
 Cholinesterase
 Copper

Lactate
 Lead
 Lipoprotein (a)
 Protein electrophoresis (serum and urine)
 Toxicology profile- identified
 Toxicology profile- unidentified
 Zinc
 Urinary β₂-microglobulin (24 hour excretion)
 α₁ - antitrypsin
 High sensitive CRP (hsCRP)
 Haptoglobin

Endocrine

Highly Specialized Test:

1,25 (OH)₂ cholecalciferol
 17-OH progesterone
 25 (OH) cholecalciferol
 ACTH
 Aldosterone
 Androstenedione
 Catecholamines -
 (Epinephrine and norepinephrine in plasma and urine)
 Cortisol
 C-peptide
 Dehydroepiandrosterone sulphate (DHEAS)
 Dehydroepiandrosterone
 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
 Parathyroid hormone (PTH)
 Plasma rennin activity (PRA)
 Progesterone
 Prolactin
 T3 (free and total)
 T4 (free and total)
 Testosterone
 Urinary free cortisol (24 hour)
 Urinary HIAC
 Urinary VMA

Tumor Markers

CA 125	PSA (free)
CA 15-3	Thyroglobulin
Ca 19.9	
Carcinoembryonic antigen (CEA)	
Prostatic Specific Antigen (PSA)	

A.2 Haematology:

Routine tests:

- Full Blood Counts – manual or with analyzer
- Reticulocyte count
- Erythrocyte Sedimentation Rate (ESR) – manual or automated
- Plasma and urine hemoglobin
- Urine haemociderine
- Methhaemoglobin, cryoglobulin in plasma
- Coagulation tests- prothrombin and partial thromboplastin time. Manual or semi/fully automation
- Euglobin clot lysis time
- Bleeding and clotting time

Special Tests:

- Haemoglobin electrophoresis and quantification. HPLC method
- Screening for PNH
- Screening for red cell membrane defects – OF and related tests
- Screening for G6PD deficiency
- NAP score
- LE cells
- Red cell inclusion bodies
- Serum B2 microglobulin
- Serum B12, Folate and red cell folate levels
- ANA and Ds-DNA detection, rheumatoid factor
- Serum Haptoglobin level
- FDP and D-Dimer
- Special stains in leukaemia diagnosis
- Coagulation tests – thrombin time, clot solubility test, factor correction, inhibitor detection, Factor assay
- Blood Pictures
- Screening for lupus antibodies, anticardiolipin antibodies

Highly Specialized Tests:

- Bone marrow biopsy and trephines
- Electron microscopic diagnosis of red cell membrane defects and other Cellular defects
- DNA studies and SDS page
- Gene studies and RFLP for detection of inherited disorders
- Cytogenetic studies for diagnosis, prognosis and disease follow up
- Flowcytometric studies on membrane markers
- Bone marrow transplantation and related investigations
- Screening for hereditary thrombophilic conditions
- Immuno-histochemical staining of bone marrow slides
- Platelet function tests on the Aggregometer
- Coagulation factor and V W factor assays and inhibitor assay
- FISH technique
- PCR technique
- Quantification of red cell enzymes
- Transferring receptor level
- Thrombo-elastography
- Bone marrow transplant related tests

A.3 Microbiology and Serology:

Routine Tests:

- Bacteriology culture:
Urine, Blood, CSF and other sterile fluids, Pus, Sputum, throat, Wound, Eye, Ear and other swabs, s tools for *Vibrio cholerae*, *Salmonella*, *Shigella* and clot culture for enteric fever and the ABST for a bove.
Microscopy of high vaginal swab
CSF microscopy
UFR
- Bacterial serology:
ASOT, Paul Bunnell Test and SAT
- Mycology:
Scrapings of skin/nails for microscopy
- Parasitology:
Blood – malaria parasites, blood concentration test for microfilaria
Stools – stools for concentration for parasites, ova and cysts
Vaginal swabs: - Trichomonas
Tuberculosis - Sputum for AFB
- Leprosy:
Modified ZN stain for nasal discharge/biopsy

Special tests:

- Bacteriology cultures Diphtheria, Pertussis, *Legionella*, stools for *Campylobacter* and their ABST
Anthrax spores detection
- MIC
- Bacterial serology
Brucella agglutination, Weil felix test, Chlamydia serology, serology for Mycoplasma, Legionella urine antigen

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- Mycology:
Scrapings of skin/nail for culture, blood, sputum microscopy and culture
- Parasitology:
Filarial FAT, testing for toxoplasma, pus and body fluids for amoeba culture and stools for amoeba culture, tape worm segments and worm egg counts
- Tuberculosis:
Sputum and other body fluids for TB culture
- Sexually transmitted diseases: Microscopy, culture and HIV investigations

Highly specialized tests:

- Bacteriology culture:
Anaerobic culture, *Leptospira* MAT and culture, Serotyping of *Salmonella*, biotyping and serotyping of *Vibrio cholerae*
- Disinfectant testing, biological test for autoclave efficacy
- Mucology:
Biopsy for histology, pus for Actinomycosis and maduramycosis, serology for Aspergillosis, Histoplasmosis
- Virology:
Virus isolation, molecular techniques and any technique that involves live virus Antigen and antibody detection assay by IF, HI, ELISA and PHA
- Microscopy and other tests of rabies
- RT PCR, PCR

A.4 Histopathology:

Routine Tests:

- Haematoxyline and eosine for histology

Special Tests:

- Histochemistry: Special stains like – Zeil Neilson for TB, Modified Zeil Neilson, PAS/Diastase, Silver Methanamine, Massons Trichrome, Congo Red, Elastic vangieson, Giemsa, Masson Fontana, Alcian blue, Pearl stain, PTAH, Other rare Grocotts Silver Methanamine.
- Frozen section examination
- Cell Block Examination
- Immunohistochemistry (commonly used markers)– Epithelial Marker- Cytokeratin, EMA
B Cell Marker
T Cell Marker
- Neuro Origin { S 100
NSE
- Breast { Oestrogen + Progesteron
HER 2 NEU
- Soft tissue { Desmin,
Smooth muscle action
CD 99

Highly Specialized Tests:

- Flow cytometry
- EM examination
- Immuno flurorescence

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A.5 Cytopathology:

Routine Tests:

- Pap Stain
- Haematoxyline + Eosin
- Giemsa
- Cell Block

Special Tests:

- Immunocytochemistry

A.6 Immunology:

- All the tests are highly specialized tests

A.7 Molecular Biology:

- All the tests are highly specialized tests

A.8 Pharmacology:

- All the tests are highly specialized tests

A.9 Nuclear Medicine (*in-vitro* tests):

- All the tests are highly specialized tests

A.10 Andrology:

Routine Tests:

Seminal Fluid Analysis (SFA)

Special Tests:

Sperm processing for Intra Uterine Insemination (IUI)

Sperm Freezing

A.11 Embryology:

Highly Specialized Tests:

Invitro Fertilization Techniques

Embryo Freezing

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