SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

QUESTIONNAIRE
for ACCREDITATION *of*
MEDICAL / CLINICAL LABORATORIES

Instructions to the Applicant:

1. Please fill the questionnaire on your own judgment of activities.
2. Procedures need not always to be documented unless otherwise specified but may be in the form of Guidelines or Formats

ACCREDITATION SCHEME FOR MEDICAL TESTING LABORATORIES

QUESTIONNAIRE

This questionnaire is a self-assessment check list to assess the readiness of your laboratory for an assessment by SLAB.

Questionnaire Completed By

Name: _____

Position: _____

Name of the medical/clinical laboratory: _____

Signature: _____ Date: _____

01. Management System

Does your laboratory have a quality policy and general procedures manual **Yes** ☐ **No** ☐

Does the manual contain / refer to ?

Scope of laboratory work	Yes/ No
Quality policy statement	Yes/ No
Document control procedure	Yes/ No
Procedure for control of records	Yes/ No
Corrective action procedure	Yes/ No
Preventive action procedure	Yes/ No
Procedure for service agreements	Yes/ No
Procedure for selecting and evaluating referral laboratories and consultants	Yes/ No
Procedure for management of complaints or other feedback	Yes/ No
Procedure for identifying and managing nonconformities	Yes/ No
Procedure for internal auditing	Yes/ No
Management review	Yes/ No
Procedure for ensuring quality of examination results	Yes/No
Procedure for the selection and purchasing of external services and supplies	Yes/ No
Training	Yes/ No
Procedure for the selection, purchasing and management of equipment	Yes/ No
Procedure for pre-examination activities	Yes/ No
Procedure for release of results	Yes/ No
Procedure for release of examination results	Yes/ No
Procedure for laboratory information management	Yes/ No
Job descriptions	Yes/ No

Please enclose a copy of the manual

Does the laboratory maintain records for

Records of pre-examination	Yes/ No
Records related to maintenance of equipment	Yes/ No
Records of quality assurance	Yes/ No
Training records	Yes/ No
Records related to competence development	Yes/ No

Please enclose example copies of some of these.

02. Accommodation

Brief description of the testing laboratory

(Please include number of rooms, approximate size of them and any special features)

Please enclose a sketch of the laboratory layout.

Are adjacent laboratory sections effectively separated? Yes ☐ No ☐

Are environmental conditions maintained? Yes ☐ No ☐

Temperature range = ^{0}C

Relative humidity range = %

Is temperature monitored?

☐ Continually

☐ Occasionally

☐ Not at all

Is relative humidity monitored?

☐ Continually

☐ Occasionally

☐ Not at all

Are environmental conditions recorded? Yes ☐ No ☐

Are communication system provided to the laboratory Yes ☐ No ☐

03. Equipment and Reference Materials

Operation of equipment

Are equipment operated by authorized personnel Yes ☐ No ☐

Does the laboratory have all items of equipment required for the provision of services covered by the scope of accreditation Yes ☐ No ☐

Equipment Inventory

Is there an up-to-date inventory of all items of reagents and consumables? Yes ☐ No ☐

What forms are used and what information provided?

Please enclose an example page.

Calibration

Are items of measuring and testing equipment calibrated regularly? Yes ☐ No ☐

Are records kept of these calibrations? Yes ☐ No ☐

Is there a well-defined system for scheduling future calibrations? Yes ☐ No ☐

In-house Checks

Is ancillary equipment checked regularly? Yes ☐ No ☐

Are records kept of these checks? Yes ☐ No ☐

Is there a well-defined system for scheduling future checks? Yes ☐ No ☐

Equipment Maintenance

Is there a documented procedure for preventive maintenance? Yes ☐ No ☐

04. Operational Test Methods and Procedures

Sources
What test methods are used?

☐ Established text books / Journals ☐ In –house methods

☐ National or Regional Journals ☐ Others

Details of others

Please enclose a copy of test methods/procedures manual.

Arrangement for up-dating test methods manual?

Availability

Are examination methods available in documented form? Yes ☐ No ☐

Are examination methods available at Work Stations? Yes ☐ No ☐

Adherence

Are test methods followed as documented? Yes ☐ No ☐

What supervision is applied to ensure adherence to details of test methods?

Collection of Primary Sample

Is sampling performed.

☐ By authorized personnel

☐ By others not under laboratory supervision, Please specify

Is there a primary sample collection manual? Yes ☐ No ☐

Operating Procedures

Are procedures for receipt, labelling, processing, storing and reporting of samples documented?

Receipts Yes ☐ No ☐

Labelling Yes ☐ No ☐

Processing Yes ☐ No ☐

Storage Yes ☐ No ☐

Reporting Yes ☐ No ☐

Are procedures for preparing standards solutions and materials documented? Yes ☐ No ☐

Disposal of dangerous materials, if any Yes ☐ No ☐

Uncertainty of Measurement

Has the laboratory estimated uncertainty of measurement for the tests applied? Yes ☐ No ☐

05. Quality Assurance

Has the laboratory developed a PT/inter-laboratory comparison plan Yes ☐ No ☐

Has the laboratory participated in APLAC/EQA/ any inter laboratory comparison programmes for the tests applied ? Yes ☐ No ☐

If the Laboratory has not participated in PT/inter-comparisons, list down those tests

What internal procedures are used to monitor validity of testing operations?

☐ Intra-laboratory programs? Details:

☐ True blanks ☐ Replicates

☐ Check samples ☐ Mutual methods

☐ Standard reference materials

Have precision data and limits of detection (Where relevant) been calculated for all methods based on internal quality control data? Yes ☐ No ☐

Are these recorded? Yes ☐ No ☐

Please enclose recorded evidence of the above results.

06. Records and Test Data

How is test data recorded?

- ☐ In workbooks
- ☐ Ink or ball pen
- ☐ Proforma worksheets
- ☐ Pencil
- ☐ Plain paper

How frequency are calculations & data transfers checked?

- ☐ Full check on all calculations and transfers
- ☐ Regular partial check %
  (Enclose statistical justification for partial checks)
- ☐ Occasional checks (not acceptable)
- ☐ No regular check (not acceptable)

How is test data stored?

- ☐ In workbooks
- ☐ Pro-forma worksheets
- ☐ In files
- ☐ On computer
- ☐ Other (details please)

Can Test Data be readily retrieved starting from?

- ☐ Client name
- ☐ Project name
- ☐ Date of test
- ☐ Issued test report
- ☐ Other (specify)

Please enclose samples copies of examples of such data.

Please attach a copy of the report of your internal audit together with corrective action records.

Please attach a copy of the minutes of the last management review

07. Internal Audit and Management Review

Date/schedule of last internal audit?

Has all requirements of ISO 15189: 2012 covering all activities of laboratory audited at least once in last one year? Yes ☐ No ☐

Has the laboratory covered all the locations including collection centers in the audit? Yes ☐ No ☐

Has Pre and post examination activities included in the audit schedule? Yes ☐ No ☐

Date of last Management review?

08. Test Reports

Reports issued

☐ To statutory authorities ☐ Internal reports only

☐ To all clients ☐ At clients request only

Frequency of issue of test reports

Expected ☐ or Actual ☐

Monthly rate of issue is:

☐ Less than 500 ☐ 1000 - 8000

☐ Less than 1000 ☐ More than 8000

Format provides for

- ☐ Name of laboratory
- ☐ Serial No:
- ☐ Date of issue
- ☐ Identity of the patient
- ☐ Identity of the Requestor
- ☐ Approved signatory
- ☐ Statement of compliance of sample with specification
- ☐ Results
- ☐ Confidence limits and limits of detection
- ☐ Comments necessary to interpret results
- ☐ Examination details
- ☐ Professional advice on use of results
- ☐ Test method
- ☐ Units of measurement
- ☐ Sample collection details

Issue & Retention

Are report typed ☐ Computer-printed ☐ Transmitted direct form computer ☐

Are copies retained? Yes ☐ No ☐

Does a copy carry full information given on original, including signature? Yes ☐ No ☐

Is a register of test reports kept? Yes ☐ No ☐

How are retained copies filed?

☐ In numerical sequence ☐ In client's name ☐ In project file

Please enclose copies of typical reports (3-5) and associated work book (page)/Work sheet.

09. Information/details provided as part of application

- ☐ Application for accreditation.
- ☐ Scope of accreditation with Test methods, range of testing and MU
- ☐ Laboratory's documented Quality System (Quality Manual, Procedures Manual, Primary Sample Collection Manual etc).
- ☐ Two signed copies of Terms and Conditions of maintaining SLAB accreditation (ML-RG(P)-03)
- ☐ Details of Primary Sample Collection Facilities
- ☐ Legal identity (Registration details of the Laboratory)
- ☐ Examples of job descriptions and training records.
- ☐ Organization chart.
- ☐ A sketch of the accommodation.
- ☐ List of equipment / Reference material used with details of Traceability.
- ☐ Key calibration certificates.
- ☐ Laboratory procedures and test methods.
- ☐ PT Plan (Please refer Annex A)
- ☐ Copies of relevant test reports (3-5) and associated work book (Page)/Work sheet.
- ☐ Internal audit report and corrective action records.
- ☐ Management review records.
- ☐ Cross reference matrix to ISO 15189: 2012 (Please refer Annex B)
- ☐ Application Fee

Verified the above details and confirmed the availability of all required documents/details as part of application form.

Signature of Head of the laboratory / Director _____

Name & Designation _____

Date & Place _____

Annex A
(Informative)

Three Year PT / Inter-laboratory comparison Plan

Laboratory Name	
Accreditation Number (if accredited by SLAB)	
Field of Testing	
Three Year Period of Participation	**From** **To**

Field of Testing	**Products group/s**	**Test Parameter/s**	**Participation plan (Year wise)**			**Name of PT Provider**	**Remarks by the laboratory**
			Year-1	Year-2	Year-3		

If laboratory organizes Inter-laboratory comparison programmes, provide justification:-

Annex B
(Informative)

Example for Cross Reference Matrix

Clause Number of ISO 15189	**Quality Manual** (Section / page)	**Standard Operating Procedure/ Work Instructions** (Identification number of procedure/ Work Instruction)	**Formats/ Plans** (Identification number of format/ plan)	**Other documents**
4.1.1.1	Chapter 04, page 15/45	No	No	
4.1.1.2	Chapter 04, page 16/45	No	No	Company registration certificate
4.1.1.3				
4.1.1.4				
4.1.2.1				
4.1.2.2				
4.1.2.3				

Note: Laboratory should develop cross reference matrix for both management and technical requirements