



**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: _____

Signature: _____

Date: _____

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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 with Technical Director's Endorsement Yes/ No

Document Control Procedure (Internal and External) Yes/ No

Procedure for Control of Records Yes/ No

Corrective Action Procedure Yes/ No

Preventive Action Procedure Yes/ No

Procedure for Review of Contracts Yes/ No

Procedure for evaluation of Referral Laboratories Yes/ No

Procedure for Handling Complaints Yes/ No

Procedure for Control of Non-conforming Testing Work Yes/ No

Internal Auditing Procedure Yes/ No

Management Review Procedure Yes/ No

Procedure for Quality Assurance Yes/No

Procedure for External Services and Supplies Yes/ No

Procedure for Training Yes/ No

Procedure for safe Handling and use of Test Equipment Yes/ No

Procedure for Calibration of Equipment Yes/ No

Procedure for Handling of Test / Calibration Items Yes/ No

Procedure for Release of Results 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.

| | | | | |
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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 = °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 equipment? 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

Equipment List

On the following page, please list all significant items of equipment, providing details of make, model, serial number, range, if applicable and calibration status (date of last calibration, name of calibrating authority), if available.

The preferred order is: a) Reference equipment - Weights, balances, themometres etc;

b) Testing equipment - auto analyzers, spectrophotometers, etc;

c) Ancillary equipment – autoclaves, centrifuge etc;

List of major test equipment available for use

| Sl no | Name of equipment | Model/ type/ year of make | Receipt date & date placed in service | Range and accuracy | Date of last calibration | Calibration due on * | Traceability** |
|-------|-------------------|------------------------------|---|-----------------------|-----------------------------|-------------------------|----------------|
| | | | | | | | |

List of reference materials available for use

| Sl. no. | Name of reference material/ strain/ culture | Source | Date of expiry/ validity | Traceability** |
|---------|--|--------|--------------------------|----------------|
| | | | | |

* the laboratory to decide the calibration interval based on ISO 10012

** please indicate the traceability to National/ International standards through unbroken chain of Accredited laboratories

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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

05. Quality Assurance

Proficiency Testing

Does this laboratory participate in any inter laboratory comparison programmes? Yes No

Details of organization, nature and frequency of programmes;

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.

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06. Records and Test Data

How is Test Data Recorded?

- | | |
|--|--|
| <input type="checkbox"/> In workbooks | <input type="checkbox"/> Ink or ball pen |
| <input type="checkbox"/> Proforma worksheets | <input type="checkbox"/> Pencil |
| <input type="checkbox"/> 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?

- | | |
|---|---|
| <input type="checkbox"/> In workbooks | <input type="checkbox"/> Pro-forma worksheets |
| <input type="checkbox"/> In files | <input type="checkbox"/> On computer |
| <input type="checkbox"/> Other (details please) | |

Can Test Data be readily retrieved starting from?

- | | |
|--|---|
| <input type="checkbox"/> Client name | <input type="checkbox"/> Project name |
| <input type="checkbox"/> Date of test | <input type="checkbox"/> Issued test report |
| <input type="checkbox"/> 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

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

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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.

| | | | | |
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08. Miscellaneous

Have you enclosed copies of the following?

- Application for accreditation.
- Tests for which accreditation is sought.
- Laboratory's documented Quality System (Quality Manual & Procedures Manual).
- Examples of job descriptions and training records.
- A staff organization chart.
- A sketch of the accommodation.
- Equipment list.
- Key calibration certificates.
- Laboratory procedures and test methods.
- Examples of quality control data.
- Examples of sample register page and relevant test records.
- Copies of relevant test reports (3-5) and associated work book (Page)/Work sheet.
- Internal audit report and corrective action records.
- Management review records.

