

Accreditation Education Research and Scientific Services Center, Nepal

Application for Testing Laboratory

Issue No.: 01; Issue Date: July 01, 2012

Amendment No. :00; Amendment Date:.....

1. Laboratory Details

Name of the laboratory : _____

Address: _____

Parent Organization (If any) : _____

Website: _____

Legal Identity : _____

Contact Person: _____

Telephone No.: _____

Mobile No. : _____

Fax No. : _____

E-mail : _____

2. Application for

First Accreditation

Renewal of Accreditation

Extension of Accreditation

3. Type of Facility:

Permanent Facility

Site Facility

Mobile Facility

4. Accreditation Details (Disciplines) :

Chemical

Biological

Mechanical

Non-destructive

Electrical

Electronics

5. Scope of Accreditation (Please provide Annexure):

S. No.	Product / Material / Item tested	Specific Tests / Types of Tests	Specification / Standard Method / Technique	Range of Testing/ Limit of Detection	Measurement Uncertainty (\pm)

6. About the Organization

Chief Executive of the Laboratory _____

Quality Manager of the Laboratory _____

Contact Person of the Laboratory _____

Staff Details :

S. No.	Name & Designation	Qualification	Total Experience	Relevant Training

Authorized Signatories:

S. No.	Name & Designation	Qualification	Total Experience	Relevant Training	Authorization for which specific area of testing	Specimen Signature

Organization Chart

(a) Provide the Organization Chart of the Laboratory indicating the position of all the staff.

(b) Provide the organization chart of the parent organization indicating the position of testing laboratory (if applicable)

7. Detail of Facilities:

Equipment Details:

S. No.	Name of Equipment	Model / Type / Make	Range and Accuracy	Date of Last Calibration	Calibration Due on	Calibrated by

Reference Standards Details:

S. No.	Name of reference material/ strain/ culture/ standard	Source	Date of expiry/ Calibration validity	Traceability

8. Internal Audit and Management Review

Date of last Internal Audit _____

Date of last Management review _____

9. Details of Proficiency Testing / Inter Laboratory Comparisons:

S. No.	Product/ Material	Details of Test(s)	Date of Testing	Nodal Laboratory/ PT Provider (Accreditation Body/ Country)	Performance in terms of Z score	Corrective Action Taken (if any)

10. Application Fees

DD / Cheque No. _____

Date of Issue of DD/ Cheque _____

Amount _____

Name of Bank _____

11. Declaration by the laboratory

We declare that

- ✓ We are familiar with the terms and conditions of maintaining accreditation and will abide by them.
- ✓ We agree to comply fully with ISO/IEC 17025: 2005 for the accreditation of testing laboratory.
- ✓ We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment, verification visit (if any), surveillance and reassessment irrespective of the result.
- ✓ We agree to co-operate with the assessment team in examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of accreditation.
- ✓ We satisfy all national, regional and local regulatory requirements for operating a laboratory.
- ✓ _____ has provided consultancy for preparing towards accreditation
- ✓ All information provided in this application is true.

Signature of Laboratory Head: _____

Name & Designation _____

Date & Place: _____

----- **END** -----

Accreditation Education Research &
Scientific Services Center, Nepal

Application form for Accreditation
of Medical/Clinical Laboratories

Issue No.: 01; Issue Date: July 01, 2012

Amendment No. :00; Amendment Date:.....

APPLICATION FORM FOR ACCREDITATION OF MEDICAL/CLINICAL LABORATORIES

We apply for AERSSC accreditation of our **Medical testing laboratory** as per details given below:

First Accreditation Scope Extension Renewal of Accreditation

1. Laboratory Details

1.1 *Name of the Medical testing Laboratory*

Address _____

Telephone _____ Facsimile _____

Fax No _____ e-mail _____

NOTE If the Laboratory operates in different locations with same legal identity, separate applications are to be submitted.

1.2 *Name of Parent Organization*

(if part of an organization)

Address _____

Telephone No. _____ Fax No. _____ e-mail _____

1.3 *Legal status and date of establishment*

(please give Registration No. and name of the authority who granted the registration)

1.4 *Clients of Testing Services*

(please tick in as appropriate)

Individual Clients On contract for Corporate Clients an in-house activity

percentage percentage percentage

1.5 *Details of primary sample collection facilities*

(Please tick in ad appropriate and provide list of all facilities with complete contact details)

at Permanent facility at Site Other Locations
(Laboratory Premises) (Visit Patient) (Collection Centres)

1.6 Do you conduct Testing in the following Category
(if yes, please clearly indicate in the scope of accreditation, para 2.3, the test conducted)

- a. At Site (Undertaking testing at site of the client) Yes No
- b. Temporary Facility (when a facility is created temporarily for testing) Yes No
- c. Mobile Laboratory Yes No

1.7 Is testing Subcontracted
(if yes, please specify the subcontracted work) Yes No

1.8 Size of Laboratory
Small laboratory (< 50 Test Requests per day) Medium laboratory (51- 400 Test Requests per day) Large laboratory (> 400 Test Requests per day)

1.9 Other accreditations _____

2. Accreditation Details

2.1 Field of Testing for which accreditation is sought
(please tick as appropriate)

- | | | | |
|--|--------------------------|--|--------------------------|
| ▪ Clinical Pathology | <input type="checkbox"/> | ▪ Immunology | <input type="checkbox"/> |
| ▪ Chemical Pathology / Clinical Biochemistry | <input type="checkbox"/> | ▪ Haematology and Immunohaematology | <input type="checkbox"/> |
| ▪ Molecular Biology | <input type="checkbox"/> | ▪ Pharmacology | <input type="checkbox"/> |
| ▪ Microbiology and Serology | <input type="checkbox"/> | ▪ Nuclear medicine (in-vitro tests only) | <input type="checkbox"/> |
| ▪ Histopathology / Cytopathology | <input type="checkbox"/> | | |

2.2 If the Laboratory is already accredited, indicate the Scope & Tests for which accreditation granted

2.3 Scope of Accreditation

Sl no	Materials examined/tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	MU (\pm)

Note 1. When referring to publications of ICSH, ISH, IFCC, IUMS, WHO etc. please mention reference details (chapter/page) and year of publication as appropriate.

Note 2. Laboratories performing site testing shall clearly identify the specific tests/examination performed at site.

Note 3. Uncertainty of Measurement (MU) at a confidence probability of 95%.

3. Organization

3.1 **Senior Management** (Name, Designation, telephone, Fax, e-mail)

3.1.1 Chief Executive of the laboratory _____

3.1.2 Laboratory Director, if different from 3.1.1

3.1.3 Person responsible for the laboratory management system

3.1.4 Person responsible for technical operations

3.1.5 Authorized Representative for AERSSC _____

3.1.6 Authorized signatories for issue of test certificates and reports (please refer relevant specific criteria)

Sl no	Name & Designation of Signatory	Qualification with Specialization	Relevant Training	Authorized for which specific area of testing

Note. If opinions or Interpretations are given on test reports, please indicate such information as well with relevant qualification

3.1.6 Information regarding any individual or organization that has provided consultancy for being prepared towards AERSSC accreditation;

- a. Development of Quality Management System: _____
- b. Development of Technical Operations: _____
- c. Specific Training: _____
- d. Conducting Internal Audits: _____
- e. Other: _____

3.2 Organization Chart

3.2.1. Indicate in an organization chart the operating departments of the testing laboratory for which accreditation is being sought (please append)

3.2.2 Indicate how the testing laboratory is related to external organizations or to its own parent organization (where applicable)

3.3. Employees

3.3.1 Total number in testing laboratory for the specific field(s) applied _____

3.3.2 Total number in testing laboratory for which accreditation is being sought _____

3.3.3 Details of staff (please clearly indicate staff responsible for site testing, if applicable)

SI no	Name	Designation	Academic and Professional Qualifications*	Experience related to present work (in years)

* Please clearly indicate the field of specialization

3.3.4 If services of consultants are obtained. Please provide details.

3.3.5 If Trainees or Contracted persons are employed, Please indicate details.

4. Equipment and Reference Materials

4.1 Equipment List

please list down 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;

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**

4.2 List of reference materials

please list down all reference materials used for verification or validation of test method or technique applied for Accreditation

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

5. EQA and PT Programmes

Please list down the details of EQA or PT programmes currently participated by the Laboratory

Sl. no.	Materials examined/ tested	Specific tests/ examination performed	Test method or group of methods applied for Accreditation	EQA/PT programme	Service provider	Frequency

6. Willingness to undergo Assessment

We declare that

- 6.1 We are familiar with and will abide by the terms and conditions of maintaining AERSSC accreditation included in the agreement to be signed by both parties, which is enclosed.
- 6.2 We agree to comply fully with ISO 15189: 2012 for the accreditation of medical testing laboratory.
- 6.3 We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment, verification visit (if any), surveillance and reassessment irrespective of the result.
- 6.4 We agree to co-operate with the assessment team appointed by AERSSC for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of accreditation.

Signature of Chief Executive or his authorized representative _____

Name & Designation _____

Date & Place _____