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|  | **QAI CLA 102** |
|  | **Quality and Accreditation Institute**  **Centre for Laboratory Accreditation** |

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*Change Adapt Improve*

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| **APPLICATION FORM**  **FOR**  **MEDICAL LABORATORIES** |

**Issue No.: 03 Issue Date.: May 2019**

**CHANGE HISTORY**

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| **Sl. No.** | **Doc. No.** | **Current Issue No.** | **Revised Issue No.** | **Date of Issue** | **Reasons** |
| 1 | CLA 102 | 1 | 2 | August 2018  (27 August 2018) | Font changed |
| 2 | CLA 102 | 2 | 3 | May 2019  (20 May 2019) | Fee structure removed from the application form to make it applicable globally |
| 3 |  |  |  |  |  |
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### CONTENTS

|  |  |  |
| --- | --- | --- |
| Sl. No. | **Title** | Page No. |
| 1 | Information & Instructions for completing an Application Form | 4 |
| 2 | Application Form | 5 |

**Information & Instructions for Completing an Application Form**

1. Quality & Accreditation Institute (QAI)’s Centre for Laboratory Accreditation (CLA) offers accreditation services to medical laboratories both in India and overseas.
2. A laboratory implementing the requirements of ISO 15189:2012 is eligible to apply under Medical Laboratory accreditation program.
3. Application shall be made in the prescribed form QAI CLA 102 only. Applicant laboratory is requested to submit the following:

* Soft copy of completed application forms
* Soft copy of self-assessment tool kit along with referenced documents
* Soft copy of Quality Manual
* Prescribed application fees
* Soft copy of signed QAI CLA 002 ‘Terms and Conditions for Obtaining and Maintaining

Accreditation/ Certification’

1. Application form and self-assessment tool kit can be downloaded as a word file. Incomplete application may lead to delay in processing of your application.
2. The applicant laboratory shall provide soft copy of appropriate document(s) in support of the information being provided in this application form.
3. Laboratory is advised to familiarize itself with QAI CLA 101 ‘Information Brochure for Medical Laboratories’ and QAI CLA 002 ‘Terms and Conditions for Obtaining and Maintaining Accreditation/Certification’ before filling up this form.
4. The applicant laboratory shall intimate QAI CLA about any change in the information provided in this application such as scope applied for accreditation, personnel and location etc. within 15 days from the date of changes.

# Application Form for Medical Laboratory Accreditation

We apply for QAI CLA accreditation of our **medical laboratory** as per details given below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | First Accreditation |  |  |  | Renewal of Accreditation |

1. **Laboratory Details**

|  |  |
| --- | --- |
| **1.1** | **Name of the Laboratory** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |

Complete Address(s)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.2** | **Does the laboratory operate from different locations having same legal identity within the city?** | |  | **Yes** | |  | **No** |  |
|  |  |  | |  |  |  |
|  |  | |  |  | |  |  |  |
|  | If yes, whether application for accreditation covers all locations | |  | **Yes** | |  | **No** |  |
|  |  |  | |  |  |  |
| **1.3** | **Do you conduct Testing in the following Category** | |  |  |  |  |  |
|  | (if yes, please clearly indicate in the scope of accreditation, sl. no. 2.2, the test conducted) | | | | | | |
|  | a. | Site Facility (when undertaking testing at site of the customer) |  | **Yes/No** | | | |
|  |  |  | | | | | |
|  | b. | Permanent Facility |  | **Yes/No** | | | |
|  |  |  |  |  |  |  |  |
|  | c. | Mobile Laboratory |  | **Yes/No** | | | |

* 1. **Name of the Parent Organisation** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(if laboratory is a part of a bigger organisation)

Telephone No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. **Legal identity of the laboratory and date of establishment** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­

(Please give registration number and name of authority who granted the registration. Copy of

the certificate shall be enclosed)

* 1. **Type of laboratory by service**

Open to others Yes/No

Partly open to others Yes/No

An in-house activity Yes/No

* 1. **Category for which accreditation is being sought**

**(please put a cross in the box)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Very Small Laboratory |  |  | Large Laboratory |  |
|  |  |  |  |  |  |
|  | Small Laboratory |  |  | Very Large Laboratory |  |
|  |  |  |  |  |  |
|  | Medium Laboratory |  |  | Multiple Location Laboratory |  |

* 1. **Number of collections centers**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Upto 10 |  | 11- 50 |  | 51- 100 |  | More than 100 |  |

* 1. **Details of primary sample collection facilities including franchise or any other source of collection sample other than the permanent facility**

(Provide list of all facilities with complete contact details. List of facilities shall segregate in

terms of ownership, management and franchisee.)

* 1. **Other accreditations­**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Details of Accreditation Sought**

**2.1 Disciplines for which accreditation is sought** (please put a cross in the appropriate box)

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  | Clinical Biochemistry |  |
|  |  |  |
|  | Clinical Pathology |  |
|  |  |  |
|  | Haematology and Immunohaematology |  |
|  |  |  |
|  | Microbiology and Serology |  |
|  |  |  |
|  | Histopathology |  |
|  |  |  |
|  | Cytopathology |  |
|  |  |  |
|  | Genetics |  |

Note 1. Laboratories performing site testing shall clearly identify the specific tests/

examination performed at site.

Note 2. Laboratories are encouraged to provide estimates of Measurement of

Uncertainty (MU) / % CV. MU should be calculated at a confidence probability of 95%.

**2.2 Scope of Accreditation**

**Discipline: Clinical Biochemistry**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sl. No. | Type of Samples examined/  Tested | Specific tests/ examination performed | Standard (method), Principle /Methodology or Technique used | Range of testing/ Limit of detection | %CV / MU (± ) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Discipline: Clinical Pathology**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sl. No. | Type of Samples examined/  Tested | Specific tests/ examination performed | Standard (method), Principle /Methodology or Technique used | Range of testing/ Limit of detection | %CV / MU (± ) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Discipline: Haematology and Immunohaematology**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sl. No. | Type of Samples examined/  tested | Specific tests/ examination performed | Standard (method), Principle /Methodology or Technique used | Range of testing/ Limit of detection | %CV / MU (± ) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Discipline: Microbiology & Serology**

|  |  |  |  |
| --- | --- | --- | --- |
| Sl. No. | Type of Samples examined/ tested | Specific tests/ examination performed | Standard (method), Principle /Methodology or Technique used |
|  |  |  |  |
|  |  |  |  |

**Discipline: Histopathology**

|  |  |  |  |
| --- | --- | --- | --- |
| Sl. No. | Type of Samples examined/ tested | Specific tests/ examination performed | Standard (method), Principle /Methodology or Technique used |
|  |  |  |  |
|  |  |  |  |

**Discipline: Cytopathology**

|  |  |  |  |
| --- | --- | --- | --- |
| Sl. No. | Type of Samples examined/ tested | Specific tests/ examination performed | Standard (method), Principle /Methodology or Technique used |
|  |  |  |  |
|  |  |  |  |

**Discipline: Genetics**

|  |  |  |  |
| --- | --- | --- | --- |
| Sl. No. | Type of Samples examined/tested | Specific tests/ examination performed | Standard (method), Principle /Methodology or Technique used |
|  |  |  |  |
|  |  |  |  |

1. **Organisation**

**3.1 Senior Management** (Name, Designation, Telephone, E-mail)

3.1.1 Chief Executive/ Director/ Head of the laboratory \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.1.2 Laboratory Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.1.3 Quality Manager\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.1.4 Contact person for QAI-CLA \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**3.2 Organisation Chart**

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

3.2.2 Indicate how the testing laboratory is related to its own parent organisation (where applicable)

**3.3 Human Resources**

3.3.1 Details of staff

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sl. No. | Name | Designation+ | Academic and Professional Qualifications\* | Experience related to present work (in years) |
|  |  |  |  |  |
|  |  |  |  |  |

+ Quality Manager is advised to have completed a training course on ‘Internal Audit & Quality Management System as per ISO 15189’

\* Please clearly indicate the field of specialisation

1. **Equipment and Reference Materials:**

**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 \* | Calibrated by\*\* |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**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 or ILAC-G24

\*\* Please mention name of calibration agency. In case the equipment is calibrated in-

house, same needs to be clearly indicated under this column.

1. **Proficiency Testing**

Participation in PT / any other Inter Laboratory Comparison/EQAS(for details and requirements please refer to ISO/ IEC 17043)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Sl. No. | Product/ Material | Details of Test(s)/ examination | Date of Testing/ examination | Organizing body | Performance in terms of z score or any other criteria | Corrective action taken (if required) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. **Application Fees**
   1. Application fees (INR/USD).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   2. DD/At par cheque number/ bank transfer reference number\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Declaration by the laboratory**

##### **We declare that**

**7.1** We are familiar with the Terms and Conditions of Maintaining Accreditation/ Certification (QAI CLA 002), which is signed and enclosed with the application. We also undertake to abide by them.

**7.2** We agree to comply fully with the requirements of ISO 15189 for the accreditation of medical laboratory.

**7.3** We agree to comply with accreditation procedures and pay all costs for any assessment carried out irrespective of the result.

**7.4** We agree to co-operate with the assessment team appointed by QAI CLA 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.

**7.5** We undertake to satisfy all national, regional and local regulatory requirements for operating the laboratory.

**7.6** No adverse action has been initiated / taken against the laboratory in the past. (If yes, please provide the details with present status ………………………………………………………..)

**7.7** All information provided in this application is true to the best of our knowledge and ability.

Signature of CEO/Laboratory Head/ Laboratory Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name & Designation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date & Place \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Quality and Accreditation Institute

Centre for Laboratory Accreditation

416, Krishna Apra Plaza, Sector 18

Noida-201301, U.P., India

Tel.: +91-120 4113234

Website: www.qai.org.in

Twitter@QAI2017