**QAI CLA 112**

**Quality and Accreditation Institute**

**Centre for Laboratory Accreditation**

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*Change Adapt Improve*

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| **APPLICATION FORM** **FOR** **QAI CERTIFICATION OF** **BASIC COMPOSITE MEDICAL LABORATORIES (QCBCML)** |

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| --- | --- |
| **Issue No. : 02** |  **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 112 | 01Nov. 2018 | 02 | May 2019(10 May 2019) | Fee structure modified‘Declaration by laboratory’ modified to include certain terms and conditions. |
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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. A laboratory performing the tests covered under Basic Composite Medical Laboratory (BCML) in Gazette notification G.S.R. 468(E) dated 18th May, 2018 by MOHFW to amend Clinical Establishments (Central Government) Rules, 2012 is eligible to apply under this program of Certification of BCML. A laboratory performing tests outside BCML scope can also apply subject to availability of required authorised signatory as per applicable regulation.
2. Application shall be made in the prescribed form QAI CLA 112 only. Applicant laboratory is requested to submit the following:
* Soft copy of completed application form
* Soft copy of assessment tool
* Prescribed application fees
* Soft copy of signed QAI CLA 002 ‘Terms and Conditions for Obtaining and Maintaining

 Accreditation / Certification’

1. Application form and assessment tool can be downloaded from website www.qai.org.in. 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 111 ‘Information Brochure of QAI Certification for Basic Composite Medical Laboratories’ (QCBCML).
4. The applicant laboratory shall intimate QAI CLA about any change in the information provided in this application such as scope applied for certification, personnel and location etc. within 15 days from the date of changes.

**Application Form of QAI Certification for Basic Composite Medical Laboratories (QCBCML)**

We apply for QAI CLA Certification for **Basic Composite** **Medical Laboratory** as per details given below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **First Certification** |  |  |  | **Renewal of Certification** |

1. **Laboratory Details**

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

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

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

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **1.2** | **Do you conduct Testing in the following Category**  |  |  |  |  |  |
|  | (if yes, please clearly indicate in the scope of certification, sl. no. 2.1, 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** |

**1.3 Name of the Parent Organisation** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (if laboratory is a part of a bigger organisation)

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

**1.4 Goods and Service Tax (GST) No.** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1.5 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)

**1.6 Type of laboratory by service**

Open to others Yes/No

 Partly open to others Yes/No

 An in-house activity Yes/No

**1.7 Other certification­(s)**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Details of Certification Sought**

 **2.1 Scope of Certification**

**Discipline: Biochemistry**

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

**Discipline: Haematology**

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

**Discipline: Medical Microbiology & Serology**

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

1. **Organisation**
	1. **Senior Management** (Name, Designation, Telephone, E-mail)
		1. Chief Executive/ Director/ Head of the laboratory \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
		2. Contact person for QAI-CLA \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	2. **Human Resources**
		1. Details of staff

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

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 | Date of last calibration | Calibrationdue on  | Calibrated by |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**List of reference materials available for use:**

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

1. **Proficiency Testing**

Participation in PT / EQAS/ any other Inter Laboratory Comparison

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 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).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	2. DD/At par cheque number/ bank transfer reference number\_\_\_\_\_\_\_\_\_\_\_\_\_

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

1. **Declaration by the laboratory**

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

* 1. We are familiar with the terms and conditions of maintaining certification as described below in this application form (sl. no. 7.2 to 7.8). We also undertake to abide by them.
	2. We agree to comply fully with the requirements of QAI Certification for Basic Composite medical laboratory.
	3. We agree to comply with certification procedures and pay all costs for any assessment carried out irrespective of the result.
	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 certification.
	5. On grant of certification, the laboratory shall:
1. claim certification in only those premises, services, tests for which it has been certified
2. not state its certification in a manner as to be considered misleading or unauthorized and bring QAI to disrepute
3. not use QAI certification mark or certificate for promotional or publicity purposes in a way that QAI may consider to be misleading
4. use certification only to indicate that it has met the relevant standards and does not imply that a product or service is approved by QAI
5. make reference to certification in its documents, brochures or advertising only in compliance with the requirements of QAI.
	1. QAI may suspend or withdraw certification of certified laboratory/ stop processing application of an applicant laboratory, as per QAI policy, on one or more of the following grounds:
6. an applicant laboratory claiming to be QAI certified
7. during a surveillance (surprise check) or re-assessment, laboratory does not comply with the certification requirements
8. non-payment of certification expenses like assessment or surveillance or re-assessment charges and certification fees
9. not applied three months before the expiry of certification and QAI has not been able to take a decision for renewal of certification
10. non-cooperation with QAI
11. refusal to allow examination of relevant documents and records by QAI & its assessors
12. denial of access to QAI & its assessor to its premises under application/ certification
13. wrong representation of scope of certification
14. misuse of QAI logo/ certification mark or its use after expiry of certification
15. misleading reporting of facts
16. activity bringing disrepute to QAI
17. result of complaint analysis or any other information, which indicates that the laboratory no longer complies with requirements of QAI.
	1. QAI absolves itself of any legal or financial liability arising out of any act involving any

 accidental or consequential damages to personnel/equipment at any time.

* 1. We undertake to satisfy all national, regional and local regulatory requirements for operating the laboratory.
	2. No adverse action has been initiated / taken against the laboratory in the past. (If yes, please provide the details with present status ………………………………………………………..)
	3. 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

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