QAI CIA 102

Quality and Accreditation Institute

Centre for International Accreditation

Change Adapt Improve

APPLICATION FORM
FOR
MEDICAL LABORATORIES

Issue No.: 10 **Issue Date.: May 2024**

CHANGE HISTORY

Sl. No.	Doc. No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1	QAI CLA 102	01	02	August 2018 (27 August 2018)	Font changed
2	QAI CLA 102	02	03	May 2019 (20 May 2019)	Fee structure removed from the application form to make it applicable globally
3	QAI CLA 102	03	04	March 2021 (17 March 2021)	Edited point 4 in information & instructions for completing an application. Added the following in application form: • Extension of Scope (Apart from scheduled Assessment) • Goods and Services Tax (GST) and MSME Registration clause added (1.6 and 1.7) • Added clause no 5. (Internal Audit and Management Review)
4	QAI CLA 102	04	05	October 2021 (9 October 2021)	Added regulatory requirements as clause 7
5	QAI CLA 102	05	06	January 2022 (19 January 2022)	Added type of legal identity in clause 1.5

6	QAI CLA 102	06	07	June 2022 (15 June 2022)	• Scope of accreditation format revised In-line with Cl. 7.8.3 of ISO/IEC 17011: 2017 • Shifting of Clause 3 Organisation to Clause 2
7	QAI CLA 102	07	08	May 2023 (19 May 2023)	Changed ISO 15189:2012 to ISO 15189:2022 in • information and instructions Clause 2 • 5.1.1
8	QAI CIA 102	08	09	November 2023 (07 November 2023)	Changed Centre for Laboratory Accreditation (CLA) to Centre for International Accreditation (CIA)
9	QAI CIA 102	09	10	May 2024 (15 May 2024)	• QAI Logo added in the header and page border added • Phone numbers added • Email added in information and instructions

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Information & Instructions for Completing an Application Form

1. Quality & Accreditation Institute (QAI)'s Centre for International Accreditation (CIA) offers accreditation services to medical laboratories both in India and overseas.

2. A laboratory implementing the requirements of ISO 15189 is eligible to apply under Medical Laboratory accreditation program.

3. Application shall be made in the prescribed form QAI CIA 102 only. Applicant laboratory is requested to submit the following:

    - Soft copy of completed application form
    - Soft copy of self-assessment cum management documentation review tool kit along with referenced documents
    - Soft copy of Quality Manual/Management System Documents
    - Prescribed application fees
    - Soft copy of signed QAI CIA 002 'Terms and Conditions for Maintaining QAI CIA Accreditation'
    - All the above information shall be sent to the given email ID: info@qai.org.in

4. Latest versions of application form and self-assessment cum management documentation review tool kit can be downloaded from the website www.qai.org.in. Incomplete application may lead to delay in processing of your application.
5. The applicant laboratory shall provide soft copy of appropriate document(s) in support of the information being provided in this application form.
6. Laboratory is advised to familiarise itself with QAI CIA 101 'Information Brochure for Medical Laboratories' and QAI CIA 002 'Terms and Conditions for Maintaining QAI CIA Accreditation' before filling up this form.
7. The applicant laboratory shall intimate QAI CIA 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.
8. The applicant laboratory shall participate satisfactorily in the Proficiency Testing (PT) programme conducted by any accredited/ recognised PT provider in accordance with ISO/IEC 17043. In cases, where formal accredited/ recognised PT programmes are not available, the laboratory shall make use of alternate approaches prescribed in ISO 15189.

Application Form for Medical Laboratory Accreditation

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

☐ First Accreditation ☐ Renewal of Accreditation

Extension of Scope (Apart from scheduled Assessment) ☐

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**

1.4 Name of the Parent Organisation _____
(if laboratory is a part of a bigger organisation)
Telephone No. _____ E-mail _____

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)
The laboratory shall provide a copy of appropriate document(s) in support of the legal status:

- ☐ Proprietorship firm (Bank passbook/ Account statement/ ID of the Proprietor)
- ☐ Partnership (Copy of Registration under 1932 Act)
- ☐ Company Act (Copy of Registration under 1956 Act)
- ☐ Societies Registration Act (Copy of Registration under 1860 Act)
- ☐ Indian Trust Registration Act (Copy of Registration under 1882 Act)
- ☐ Limited Liability Partnership (Limited Liability Partnership Act, 2008)
- ☐ Government (Copy of Government Notification / Declaration etc.)

1.6 Goods and Services Tax (GST) Number (Please attach a copy of GST Registration Certificate):

_____

1.7 Micro, Small and Medium Enterprises (MSME) Registration Number (Please attach a copy of Registration Certificate):

_____

1.8 Type of laboratory by service

Open to others	Yes/No
Partly open to others	Yes/No
An in-house activity	Yes/No

1.9 Category for which accreditation is being sought
(please put a cross in the box)

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

1.10 Number of collections centres

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

1.11 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.)

1.12 Other accreditations_____

2. Organisation

2.1 Senior Management (Name, Designation, Telephone, E-mail)

2.1.1 Chief Executive/ Director/ Head of the laboratory (CAB) _____

2.1.2 Laboratory Director _____

2.1.3 Quality Manager_____

2.1.4 Contact person for QAI-CIA _____

2.2 Proposed personnel competent to report, review and authorisation of results (Signing of test reports)

Sl. No.	Laboratory/ Department /Section	Name & Designation	Qualification with Specialisation	Relevant experience (in years) related to present work	Relevant Training	Part Time/Full Time (timings if part time)	Authorised for which specific area of testing

2.3 Organisation Chart

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

2.3.2 Indicate how the medical laboratory is related to its own parent organisation (where applicable)

2.4 Human Resources

2.4.1 Details of staff

Sl. No.	Name	Designation[+]	Academic and Professional Qualifications	Experience related to present work (in years)	Total Experience (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

3. Details of Accreditation Sought

3.1 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%.

3.2 Scope of Accreditation

Discipline: Clinical Biochemistry

Sl. No.	Materials or Products tested	Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and/or the techniques/ equipment used	Range of testing/ Limit of detection	%CV / MU (±)

Discipline: Clinical Pathology

Sl. No.	Materials or Products tested	Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and/or the techniques/ equipment used	Range of testing/ Limit of detection	%CV / MU (±)

Discipline: Haematology and Immunohaematology

Sl. No.	Materials or Products tested	Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and/or the techniques/ equipment used	Range of testing/ Limit of detection	%CV / MU (±)

Discipline: Microbiology & Serology

Sl. No.	Materials or Products tested	Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and/or the techniques/ equipment used	Range of testing/ Limit of detection	%CV / MU (±)

Discipline: Histopathology

Sl. No.	Materials or Products tested	Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and/or the techniques/ equipment used	Range of testing/ Limit of detection	%CV / MU (±)

Discipline: Cytopathology

Sl. No.	Materials or Products tested	Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and/or the techniques/ equipment used	Range of testing/ Limit of detection	%CV / MU (±)

Discipline: Genetics

Sl. No.	Materials or Products tested	Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and/or the techniques/ equipment used	Range of testing/ Limit of detection	%CV / MU (±)

4. 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.

5. Internal Audit and Management Review:

5.1 Date of last Internal Audit _____

5.1.1 Whether all requirements of ISO 15189:2022 covering all activities of laboratory have been audited at least once in last one year

☐ Yes ☐ No

5.2 Date of last Management Review _____

6. 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)

7. Application Fees

6.1 Application fees (INR/USD)_____

6.2 DD/At par cheque number/ bank transfer reference number_____

8. Regulatory Requirements

Furnish details of applicable Statutory/ Regulatory requirements the lab is governed by (*Please attach copies of applicable documents)*:

License/Certificate	Number and Date of issue	Valid Up to	Remarks
General:			
Bio-medical Waste Management and Handling Authorisation			
Facility management:			
Fire (NOC), if applicable based on location of the lab			
License/ Registration from Atomic Energy Regulatory Board (AERB), if applicable			

9. Declaration by the laboratory

We declare that

9.1 We are familiar with the Terms and Conditions for maintaining QAI CIA Accreditation (QAI CIA 002), which is signed and enclosed with the application. We also undertake to abide by them.

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

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

9.4 We agree to co-operate with the assessment team appointed by QAI CIA 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.

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

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

9.7 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 _____

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