CAMS/D-06

# Conformity Accreditation Management System

## Application Form for Medical Laboratories

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## AMENDMENT INFORMATION

| Sl no | Page No. | Specific reference no | Date of Amendment | Amendment made | Reasons of Amendment | Signature QM/MR | Signature Director |
|---|---|---|---|---|---|---|---|
| 01 | | | | | | | |
| 02 | | | | | | | |
| 03 | | | | | | | |
| 04 | | | | | | | |

**Contents**

## Guidance for submitting an Application Form

1. Application for seeking accreditation to be comprised of:
    - Two set of completed application form/ discipline
    - Two Sets of Self-Assessment Toolkit
    - Prescribed application fees
    - Terms & Conditions for obtaining & maintaining accreditation in formed CAMS /D-03 duly signed by representative of lab.
2. The applicant laboratory shall undertake to carry out its testing activities in such a way as to meet the requirement of ISO/IEC 17025:2017, other relevant requirements of CAMS and the regulatory authorities, as applicable at all times. It is obligatory for Lab to follow the various guideline published by CAMS for implementation of the system.
3. Applicant laboratories are advised to ensure that the latest versions of CAMS documents are available and followed by them.
4. The application fee and other necessary charges related to accreditation process is given in CAMS document CAMS/D-01 'Organization information andGeneral Information Brochure' under CAMS Finance and CAMS Fee Structure'.
5. Laboratories are advised to familiarize themselves with CAMS/D-01 'Organization information and General Information Brochure', CAMS/D-02 'Procedure for dealing with Changes in Accredited Conformity Assessment Body's Operations',CAMS/D-03 'Terms and Conditions for Obtaining and Maintaining Accreditation' before filling up this form and CAMS/D-04 "Use of CAMS symbol".
6. The applicant laboratory shall provide self attested photocopy of following appropriate document(s) in support of the legal status claimed:
    - Proprietorship firm (Trade license, self-declaration in Rs 50 stamp copy of Bank Passbook, PAN card)
    - In case of Foreign origin (other than India) local legal identity document to be submitted
    - 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
    - Government (Copy of Government Notification/ Declaration etc.)
7. The applicant laboratory shall intimate CAMS about any change in the information provided in this application such as scope applied for accreditation, personnel, and location etc. within 10 days from the date of changes.
8. CAMS expects applicant laboratories that are to be accredited to follow the test methods as mentioned in the current National or International standards or method published in national and international text book, journal and as stipulated by regulatory bodies. Where such methods do not exist, other validated methods are acceptable. In case laboratory uses in-house validated methods the validation data should be submitted along with the application.
   Lab is recommended that laboratory should participate in Proficiency testing program conducted by Accreditating agency.

9. The laboratory shall also inform CAMS in advance about any reservation with valid reason regarding appointment of Lead Assessor/ Assessor for the assessment.
10. The applicant laboratory shall be given due notice of any intended changes relating to CAMS accreditation criteria and will also be given such time, as in the opinion of CAMS is reason CAMS to carry out the necessary changes to its policies/practices & procedure(s). The laboratory shall inform CAMS when such changes have been completed.
11. The Applicant must address all particulars including scope of accreditation clearly and should be understood without any prejudice. Particularly the scope of accreditation.
12. The details of laboratory locations and the tests which the laboratory intends to cover vide CAMS accreditation must be listed clearly. The tests intended to be performed at site should be clearly identified in the scope of accreditation along with associate personnel.
13. The laboratory shall submit CAMS/D-03 duly signed by the Chief Executive or his/her Authorized Representative to CAMS along with this application form. By signing CAMS/D-03 the laboratory agrees to comply at all times with Terms and Conditions of CAMS.

14. The laboratory shall offer the CAMS or its representative cooperation in:
    a. undertaking any check to verify testing capability of the laboratory.
    b. offering access to relevant areas of the laboratory for witnessing the test being performed.
    c. examination of all relevant documentation and records.
    d. interaction with all relevant personnel.

15. The laboratory shall take all necessary actions and discharge all non- conformities raised during the assessment within the within the agreed time not exciding 60 days. The same shall be verified to the satisfaction of CAMS. The final decision on accreditation shall rest with CAMS. The application shall be kept confidential (unless required by law) by CAMS and information obtained during the processing of application, assessment visit and grant of accreditation shall be safeguarded and dealt with impartiality. Laboratories shall reframe from claiming their accreditation status to public domain, customer or regulatory authority announcement for so made CAMS.

# Application Form for Laboratory Accreditation

We apply for CAMS accreditation of our medical testing laboratory as per details given below:
Type of Services:

☐ Initial Accreditation ☐ Re-accreditation

☐ Extension of Scope

If accredited by other accredited agency, please provide accreditation certificate no. & accreditation validity (if applicable) and CAB ID:_____

**1. Laboratory Details**

| | |
|---|---|
| Laboratory Name | |
| Location | |
| Register Address | |
| Mailing Address | |
| Tel. No. | |
| Fax No. | |
| Official email Address | |

**2. Does the laboratory operate from different locations having same legal identity within the city?(√ appropriate box)**

| | | | | |
|---|---|---|---|---|
| If yes, whether application for accreditation covers all locationscomplete details have been provided for each location with respect to all clause of CAMS/D-06 of the application form. | Yes | | No | |

**3. Details of primary sample collection facilitiesincluding franchise or any other source of collection sample other than the permanent facility(√ appropriate box)**

| | | | | |
|---|---|---|---|---|
| If yes, Please provide list of all facilities with complete contact details. List of facilities shall segregated in terms of ownership, management | Yes | | No | |

**4. Type of Facility(s) applied under the scope of Accreditation (√ appropriate box)**

| | | | | | |
|---|---|---|---|---|---|
| | Permanent Facility | | Site Facility | | Movable facility |

**5. Company Legal Status (License/ Registration Number) (√ Attached Legal Status)**

| | |
|---|---|
| | Proprietorship firm. ( only one copy attached )<br>(Trade license, self-declaration in Rs 50 stamp copy of Bank Passbook, PAN card) |
| | In case of Foreign origin (other than India) local legal identity document to be submitted |
| | Partnership (Copy of Registration under 1932 Act) |
| | Societies Registration Act ( Copy of Registration under 1860 Act) |
| | Indian Trust Registration Act |
| | Government (Copy of Government Notification/ Declaration etc.) |

**6. Name of Parent Organization:**

| | |
|---|---|
| Name | |
| Register Address | |
| Tel. No. | |
| Fax No. | |
| Official email Address | |
| Service/Manufacturing | |

## 7. Name of Parent Organization:

| | |
|---|---|
| Name | |
| Register Address | |
| Tel. No. | |
| Fax No. | |
| Official email Address | |
| Service/Manufacturing | |

## 8. Accreditation Granted to the Laboratory

| Name Accreditation organization | Accreditation Number | Validity of Accreditation |
|---|---|---|
| | | |

## 9. Personnel Information

### 9.1 Head of Technical Management (However Named)

| | |
|---|---|
| Name: | |
| Designation: | |
| Relevant Experience | |
| Email: | |
| Mobile No.: | |

### 9.2 Head of Quality Management (However Named)

| | |
|---|---|
| Name: | |
| Designation: | |
| Relevant Experience | |
| Email: | |
| Mobile No.: | |

### 9.3 Dealing Person (However Named)

| | |
|---|---|
| Name: | |
| Designation: | |
| Relevant Experience | |
| Email: | |
| Mobile No.: | |

## 10. Scope of Accreditation: For Testing Laboratory Accreditation Only

Please indicate (√) the filed of testing and all the measurement parameters for which you seek CAMS Accreditation. Please tick **appropriate field testing** , and complete **a separate table**for each field:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Clinical Biochemistry | | Clinical Pathology | | Haematology and Immunohaematology | | Microbiology and Serology |
| | Histopathology | | Cytopathology | | Genetics | | Nuclear medicine (*in-vitro* tests only) |

### 10.1Scope of Accreditation

| Sl no | Group of products, materials or items tested | Specific tests performed/ parameter | * Test Method / Standard against which tests are performed | Range of Testing/ Limits of detection | Uncertainty of Measurement (±) at Value |
|---|---|---|---|---|---|
| | | | | | |

***Note:***

- Laboratories performing site testing shall clearly identify the specific tests on product(s)/ material performed at site separately.
- Measurement uncertainty shall be expressed as expanded uncertainty with 95% confidence level
- Latest test methods and standards shall be mentioned along with the year of publication of the standard and amendment, if any
- In case of enhancement of scope; it shall be specifically mentioned and clearly identified in the scope of accreditation
- In exceptional case, where the test facility is unique in nature and is the only facility available in the country, the laboratory may use the test facility without owning it but with proper justification and agreement.
- Laboratories having multiple locations in the same city shall clearly identify the scope for each location separately.

## 11. Organization Chart

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

## 12. **Authorized Signatory (**Authorized signatories for approval of test reports)

| Sl. No | Name & Designation of Signatory | Qualification with Specialization | Experience in years related to present work | Related Training | Authorized for which specific area of testing | Specimen Signature |
|---|---|---|---|---|---|---|
| | | | | | | |

## 13. Personnel details

| Sl no | Name | Designation | Academic and Professional Qualifications | Experience related to present work (in years) | Related Training |
|---|---|---|---|---|---|
| | | | | | |

**Note:**
Laboratory shall clearly indicate staff responsible for Site testing

## 14. Equipment Details

| Sl. no | Name of equipment | Model/ type/ year of make | Range and accuracy | Date of last calibration | Calibration due on * | Calibrated by** |
|---|---|---|---|---|---|---|
| | | | | | | |

* The laboratory to decide the calibration interval based on ISO D-1012 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.

## 15. Reference Materials/standards Details

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

## 16. Information about Proficiency Testing Participation related to scope parameters:

| Sl. No | Name of Test | Participation Date | PT Provider | Summary of results |
|---|---|---|---|---|
| | | | | |

## 17. Application Fees

| | |
|---|---|
| Application fees (Rs) | |
| DD / At par Cheque number | |
| GST Number | |

**information regarding the groups applied for accreditation in each discipline. Refer relevant specific criteria for more details on groups.*
***All payments made through Cheques or Demand Draft shall be made in favor of **'CAMS** payable at Kolkata.*

## 18. Terms And Conditions

1) All applications shall be submitted in word format to CAMS along with **application fees** paid as stated in CAMS/D-01
2) The signed, stamped and scanned copy of the last page of this application form (AUTHORIZATION OF THE AGREEMENT) shall also be submitted.
3) By signing the (AUTHORIZATION OF THE AGREEMENT), the applicant agrees to accept the all mentioned clauses.
4) The applicant hereby confirms that the information provided in this application form is true and correct. The applicant acknowledges that he/ she agrees to abide by the following documents/ requirements, relevant to their scope of work:
    - Relevant **CAMS Requirements**&**Guidance Documents** issued for relevant schemes covering general, administrative & technical areas. These **Requirements**&**Guidance Documents** are defined for Testing/Calibration and are available on CAMS web site;
5) To cooperate with CAMS which is necessary to enable CAMS to verify compliance with the requirements for accreditation including provision for review of documentation (including documents that provide insight into the level of independence of the applicant from any other related activities undertaken by their organization, where applicable) and access to all areas, equipment, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;
6) To claim that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;
7) To pay fees and charges as are due to CAMS in accordance with CAMS Accreditation Fee Structure (CAMS/D-01) knowing that **fees are non-refundable**;
8) Not make any statement relevant to its accreditation which CAMS may consider misleading or unauthorized and endeavor to ensure that no certificate or report, nor any part thereof, is used in a misleading manner as per accreditation requirements of conditions for the use of CAMS accreditation symbol (CAMS/D-04).
9) Upon suspension, withdrawal or expiration of its accreditation (however determined) discontinue the use of all advertising that contains reference thereto and return any issued certificates of accreditation to CAMS;
10) Inform CAMS in writing of changes or pending changes in any aspect of the applicant's status or operation that affects the applicant's legal, commercial or organizational status; organization or management (e.g., managerial staff); policies or procedures, where appropriate; premises; personnel, equipment, facilities, working environment or other resources, where significant; authorized signatories; or such other matters that may affect the accreditation body's capability, or scope of accredited activities, or compliance with the criteria, requirements and conditions for accreditation;
11) All decisions related to processing, grant of accreditation or with heal /withdrawal by CAMS would be binding for the laboratory.
12) In case of any legal dispute proceedings would be under jurisdiction of Kolkata.

**Please make sure that you have read and understood the TERMS AND CONDITIONS on this agreement**

**Authorization of the Agreement**

| | | | |
|---|---|---|---|
| Signed for and on behalf of applicant | Signature of Authorized Representative: | | Date: |
| | Full Name: | Designation: | |

| | | | |
|---|---|---|---|
| Signed for and on behalf of CAMS | Section Head Signature: | | Date: |
| | Full Name: | Designation: | |