IQAS-004

Application form for Medical Testing Laboratories

AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of Amendment	Reasons of amendment	Amendment details	Remark	Approved by
1.	--	--	28.10.2026	Periodic Review as per document control procedure	Detailing as part of periodic review	Replaces previous issue 02 dated 01.07.2024	R.S. Rana
2.							
3.							
4.							
5.							
6.							
7.							
8.							

Contents

Instructions for filling up the application.....4
Application Form 6
1. Application for getting accreditation for Testing in the following category 6
2. CAB details:. 6
3. Applicable Accreditation discipline 9
4. Scope of Accreditation 11
5. Personnel authorised for reviewing and releasing test results 11
6. Details of staff in the laboratory.....11
7. Equipment/Instruments and CRM available in the CAB 11
8. Detail of Reference Standards available in the CAB.....11
9. Internal Audit and Management Review.....11
10. Proficiency Testing.....12
11. Application Fees.....12
12. Declaration by the CAB.....13
13. List of enclosures Application Form - Check List.....14
14. Legal Entities (Annexure -I) 15
15. List of Collection Centers (Annexure -II) 16
16. Details of location for POCT equipment (Annexure -III) 17
17. Scope of Accreditation (Annexure -IV) 18
18. Personnel authorized for reviewing and releasing test results (Annexure -V) 19
19. Details of staff in the laboratory (Annexure -VI) 20
20. List of Equipment / Instrument (Annexure -VII) 21
21. Details of Reference Materials available in the Laboratory (Annexure -VIII) 22
22. Details of Participation in PT/ any other Inter Laboratory Comparison / EQAS (Annexure -IX) 23
23. List of Multiple location (Annexure -X) 24
24. Mobile Laboratory Details (Annexure -XI) 25

Instructions for filling up the application.

1. The application shall be complete in all respect in the prescribed format of IQAS-004.
2. The CAB (Conformity Assessment Body shall) refer to IQAS-001, 'General Information Brochure and Accreditation Process & Procedure,' for the applicable accreditation requirements, process, procedures, applicable fees, and other relevant information.
3. The Conformity Assessment Body (CAB) shall have adequate personnel, instruments/equipment as per the scope of accreditation along with ISO 15189:2022 /relevant latest national/international or regional standards and IQAS-001 General Information Brochure guiding documents of IQAS.
4. CABs are advised to familiarize themselves with IQAS-013 'Procedures for Dealing with Adverse Decisions' and IQAS-007 'Policy for Use of IQAS Symbol and/or IQAS Accredited CAB's for claiming Accreditation & IQAS Accredited CABs Combined ILAC MRA Mark duly signed by the top management (Chief Executive Officer/Head of the laboratory).
5. The IQAS Terms and Conditions shall be duly signed only by the Top Management (Chief Executive Officer/Head of the Laboratory) and submitted along with the Application Form. (Refer to IQAS-006 'Contractual Terms and Conditions between IQAS and CAB for Obtaining and Maintaining Accreditation')
6. CAB shall have adequate personnel, instruments/equipment as per the scope of accreditation along with latest national/international or regional standards and the latest guiding documents of IQAS.
7. CAB shall be a Legal Identity as per the law/rule of the Government of India (Refer Annexure-I of this Application form).
8. The CAB shall participate in PT/ILC, as applicable, for the applied scope and submit the PT/ILC Plan as per Annexure-I of IQAS-009. For details, refer to IQAS-009, 'Policy and Guidelines for Proficiency Testing and/or Inter-Laboratory Comparison (ILC) other than Proficiency Testing.'
9. The applicant/accredited CAB shall provide the complete address of the CAB for which accreditation is sought, including the PIN Code. Where the CAB forms part of a larger

organization or institution, the exact location of the CAB shall also be specified, including the building name, floor number, or any other unique identification necessary to clearly identify the CAB premises.

10. The applicant/accredited CAB shall use calibration methods as specified in the current National or International Standards. Where such methods are not available, other appropriately validated methods, including in-house methods, laboratory-developed methods, or modified methods, may be used. The CAB shall provide appropriate reference to the method, including the method number, issue date, or other relevant details, along with the application. Validation data shall also be submitted for all validated methods along with the application (Refer IQAS-031 Supplementary Criteria for Medical Testing Laboratories).
11. The proposed personnel for report, review and authorization of results shall meet the minimum qualification, experience and training requirements as per regulatory authorities (If applicable).

Note: - The requisite qualifications, experience and training is not sufficient. The technical competence shall be verified by IQAS assessment team during the assessment

12. CAB shall take corrective action within the time frame specified by IQAS. (Refer IQAS-001 ‘General Information Brochure and Accreditation Process & Procedure’)
13. Options opted for in Application Form is to be appropriately ticked by applicant CAB.

Note: All above IQAS documents are available on our website.

1. Application Form

(Please put √ in the applicable box)

1.1	**New Application**	☐
1.2	**For Accredited by IQAS**	
a.	Renewal of existing Accreditation	☐
b.	Scope addition/enhancement	☐
c.	Name Change	☐
d.	Premises change	☐

If yes, then please provide accreditation certificate no. & accreditation validity…….

2. CAB details:

2.1	**Name of the CAB**	
2.2	**Address** *Note: (Please indicate if the premise is owned or is acquired on lease, as applicable. Copy of proof of ownership or registered lease agreement shall be enclosed as evidence).*	
	Plot/House/Unit No./Building /Premises name	
	Street/Road**/** Locality/Area	
	City/Town/Village	
	District	
	PIN Code	
	State/UT	
	Country	
	Landmark (If any)	
2.3	**Telephone**	**Mobile:** **Landline:**
2.4	**Email Id**	
2.5	**Website (if available)**	
2.6	**Laboratory facility**	**Permanent** ☐ **Yes** ☐ **No** **Site*** ☐ **Yes** ☐ ***No*** **Mobile*** ☐ **Yes** ☐ **No** ***Provide the details of locations in case of site testing – use separate sheet.* **In case of Mobile Laboratory, details as per Annexure -XI to be provided*
2.7	**Legal Identity registered with the government**	*(refer Annexure I)*
2.7.1	**Government entity** *(Registration No. and date or Gazette Notification reference along with date)*	

2.7.2	**Limited Liability Partnership Company** *(Registration No. and date)*	
2.7.3	**Private Limited Company** *(Registration No. and date)*	
2.7.4	**Proprietary Firm/ One Person Company** *(Registration No. and date)*	
2.7.5	**Partnership Firm** *(Registration No. and date)*	
2.7.6	**GST No.** *(Registration No. and date)*	
2.7.7	**Any other Registrations which CAB desires to declare** *(Registration No. and date)*	
2.7.8	**Other Accreditations, if any (Name of Accreditation Bodies to be shared)**	
2.7.9	**Any adverse action been initiated/taken against the laboratory in the past by any Accreditation Bodies?** *(If yes, please provide the details with present status)*	**YES/NO**
2.8	**Name of the CAB as required on the Accreditation Certificate** *(Note: If the desired name of the CAB on the Accreditation Certificate is different from the Legal Identity, then the Certificate will be issued in the name of the Legal Identity only):*	
2.9	Does the laboratory operate from multiple location?	☐ **Yes** ☐ **No** *Provide the details of multiple location in the prescribed format – Annexure X*
2.10	**Detail of samples received**	
2.10.1	Does the laboratory receive samples from sample collection centers owned by the parent company?	☐ **Yes** ☐ **No** **If yes:** *Provide the details of the collection center in the prescribed format – Annexure II*
2.11	**Point of Care Testing (POCT)**	
2.11.1	Does the laboratory operate POCT?	☐ **Yes** ☐ **No**
2.11.2	Is accreditation being sought for the POCT(s)	☐ **Yes** ☐ **No** **If yes:** *Provide the location(s) of the POCT in the prescribed format – Annexure III*
2.11.3	Is the POCT covered in the Quality Manual	☐ **Yes** ☐ **No**

	to monitor the accuracy and quality of POCT?	
2.12	**Senior Management information**	
2.12.1	Chief Executive/Director/Head of the Laboratory. (As per legal entity)	

Name	
Designation	
Contact no	
Mobile no.	
Landline no.	
Email (The email id will be used to provide official information by IQAS)	

2.12.2	Person responsible for the management system	

Name	
Designation	
Contact no	
Mobile no.	
Landline no.	
Email (The Person may be contacted for any issue related to management system)	

2.12.3	Name and designation of the person responsible for technical operations	

Name	
Designation	
Contact no	
Mobile no.	
Landline no.	
Email (The Person may be contacted for any issue related to technical requirements)	

2.12.4	Contact person for IQAS (communications to be in name of this person or persons mentioned in 2.12.1/2.12.2/2.12.3. Mails to bear name of person sending the same)

Name	
Designation	
Contact no	
Mobile no.	
Landline no.	
Email	

2.13	**Organization structure**
2.13.1	If part of a larger organization, mention the position of the medical Laboratory in the organization structure. *(Attach the organization chart of the laboratory)*
2.13.2	Mention how the Medical Testing laboratory is related to its parent organization. *(if applicable)*

3. Category of the laboratory (Please select either Scheme A (3.1) or Scheme B (3.2)

(Before selecting either Scheme A or Scheme B applicable charges can be seen at IQAS-001)

3.1 Scheme A (as per footfall)

(Please put √ in the applicable box)

Category of the laboratory	
Micro Laboratory	**Up to 25 patients/ day/location**
Mini Laboratory	**26 - 50 patients/ day/location**
Small Laboratory	**51 - 100 patients/ day/location**
Medium Laboratory	**101-400 patients/ day/location**
Large Laboratory	**401-1000 patients/ day/location**
Very large Laboratory	**Above 1000 patients/ day/location**

Applicable Accreditation discipline

(Please put √ in the applicable box)

3.1.1 Clinical Biochemistry ☐ Yes ☐ No

3.1.2 Clinical Pathology ☐ Yes ☐ No

3.1.3 Hematology ☐ Yes ☐ No

3.1.4 Microbiology and Infectious Disease Serology ☐ Yes ☐ No

3.1.5 Histopathology	☐	Yes	☐	No
3.1.6 Cytopathology	☐	Yes	☐	No
3.1.7 Flow Cytometry	☐	Yes	☐	No
3.1.8 Cytogenetics	☐	Yes	☐	No
3.1.9 Molecular Biology	☐	Yes	☐	No
3.1.10 Medical Imaging	☐	Yes	☐	No
a) Projection Radiography and Fluoroscopy	☐	Yes	☐	No
b) CT	☐	Yes	☐	No
c) MRI	☐	Yes	☐	No
d) Ultrasound and Colour Doppler	☐	Yes	☐	No
e) Nuclear Medicine	☐	Yes	☐	No
f) Interventional Radiology	☐	Yes	☐	No

3.2) Scheme B (as per discipline)Applicable Accreditation discipline

(Please put √ in the applicable box)

3.2.1 Clinical Biochemistry	☐	Yes	☐	No
3.2.2 Clinical Pathology	☐	Yes	☐	No
3.2.3 Hematology	☐	Yes	☐	No
3.2.4 Microbiology and Infectious Disease Serology	☐	Yes	☐	No
3.2.5 Histopathology	☐	Yes	☐	No
3.2.6 Cytopathology	☐	Yes	☐	No

3.2.7 Flow Cytometry	☐	Yes	☐	No
3.2.8 Cytogenetics	☐	Yes	☐	No
3.2.9 Molecular Biology	☐	Yes	☐	No
3.2.10 Medical Imaging	☐	Yes	☐	No
a) Projection Radiography and Fluoroscopy	☐	Yes	☐	No
b) CT	☐	Yes	☐	No
c) MRI	☐	Yes	☐	No
d) Ultrasound and Colour Doppler	☐	Yes	☐	No
e) Nuclear Medicine	☐	Yes	☐	No
f) Interventional Radiology	☐	Yes	☐	No

4. Scope of Accreditation

Provide the details of the Scope of Accreditation in the prescribed format – Annexure IV

5. Personnel authorized for reviewing and releasing test results

Provide the details of the authorized signatories in the prescribed format – Annexure V

6. Details of CAB's staff

Provide the details of the staff in the laboratory in the prescribed format – Annexure VI

7. Details of Equipment/Instruments

Provide the details of the equipment/instrument available in the laboratory in the prescribed format – Annexure VII.

8. Detail of Reference Standards available in the CAB

Provide the details of the Reference standard available in the laboratory in the prescribed format – Annexure VIII.

9. Internal Audit and Management Review

9.1 Date of last Internal Audit ……

9.2 Whether all requirements of ISO/IEC 15189:2012/2022 covering all activities of the laboratory have been audited at ☐ **Yes** / ☐ **No**

least once in the last one year

9.3 Date of last Management Review **……**

10. Proficiency Testing

Provide the details of participation in PT/ILC/Alternate approaches in the prescribed format – Annexure IX.

11. Application Fees

11.1 Application Fees (Rs.) …….. [Rs ……... *(in words)*]

(for applicable fee calculation refer IQAS-001)

11.2 DD/at par cheque number/ bank transfer reference number and date

Note: Bank details:
INTERNATIONAL QUALITY AND ACCR SERV P L
HDFC BANK LTD
A/c. NO. 50200091849719
RTGS/NEFT IFSC: HDFC0002008

12. Declaration by the CAB

We declare that

12.1 We shall abide with the terms and conditions of IQAS for maintaining the accreditation as per the IQAS-006 Signed copy of the terms and conditions, for maintaining the accreditation, is attached.

12.2 We shall fully comply with the requirements of ISO 15189:2022 for obtaining and maintaining the accreditation of our Medical Testing Laboratory.

12.3 We agree to comply with the accreditation procedures of IQAS and pay all fees for the assessments or any other charges incurred in the process of accreditation irrespective of the result of the assessment.

12.4 We agree to cooperate and coordinate with the assessment team appointed by IQAS for the examination of all relevant documents required by the assessment team and their visits to those parts of the Laboratory that are part of the scope of accreditation.

12.5 We undertake to abide all national, regional, and local regulatory requirements for operating the Medical Testing Laboratory.

12.6 No adverse action has been initiated/ taken against the laboratory in the past by statutory authority and/or Accreditation body. (If yes, please provide the details with present status).

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

12.8 We have opted/not opted for pre-assessment.

Signature of CEO/Laboratory Head/Laboratory Director/Partner/Proprietor

Name & Designation

Date & Place

13. List of enclosures Application Form - Check List

Sr. no.	Documents/Details provided by the CAB	Yes/No
1.	Complete application in all respect duly signed by the CAB representative	
2.	Quality Manual/ Quality Management System Document as per ISO 15189: 2022 (latest version)	
3.	Application fees a) As per IQAS-001, for applied discipline, group and sub groups. b) Demand Draft / details of NEFT/at par cheque in favor of InternationalQuality and Accreditation Services (IQAS)	
4.	Copy of Legal Identity (Registration Details of the CAB)	
5.	Goods and Service Tax (GST) Number along with PAN/TAN Number	
6.	Declaration about the Consultant (if any)	
7.	Signed copy of IQAS Terms and Conditions IQAS-006 (latest issue)	
8.	PT/ILC plan, Annexure-I of IQAS-009	

Verified the above documents/details and confirmed the availability of all required documents/ details declared in Application Form.

Signature of CEO/Laboratory Head/Laboratory Director/Partner/Proprietor

Name & Designation

Date & Place

Annexure I

Legal Entities

Legal Entity -The term legal entity refers to any organisation which is constituted as per the regulation and laws under the Government of India. Legal entity could be any individual, group, person, or organisation that has legal rights and obligations related to the agreements, contracts, payments, penalties etc.

1. Who are legal entities
    a. Any and all Govt. organisations by their very nature.
    b. Public companies, Pvt. Companies, Pvt. Ltd. companies. by requirement of law.
    c. Partnership firm registered with Registrar of Partnership firms.
    d. Proprietary Firms having following
        - Bank Account (copy of bank passbook with account statement of CAB)
        - PAN card of Proprietor
        - Aadhar card of Proprietor
        - Proof that CAB premises are in name of Proprietor or rented by Proprietor.
2. Who are not Legal entities
    a. Partnership firm **NOT** registered with Registrar of Partnership firms.
    b. Proprietary Firms **NOT** having documents as mentioned in 1d above.

Note:

A. Application of only organisations that are legal entities, as described above, will be processed for further accreditation process.
B. Decision of Authorised Competent Authority of IQAS will be final with regard to application submitted and will be binding on applicant.

Annexure II

List of Collection Centers

S.No.	Name and Address of Collection Center	Name of Authorized Contact person	Phone	Email	Whether audited during the last internal audit as per ISO 15189:2022 (Yes / No)

Annexure III

Details of location for POCT equipment

S. No.	Unique ID of equipment	Name of Equipment	Location	Remarks

Annexure IV

Scope of Accreditation

(Scope to be filled separately discipline-wise)

S.No.	Product/material to be tested	Type of tests	Technique/ method/ equipment used	Range of Testing/ detection limit	%CV / Uncertainty of Measurement	Permanent / Site / Mobile

Annexure V

Personnel authorized for reviewing and releasing test results

S.No.	Name	Designation	Qualification with Specialization	Relevant experience (in years) related to present work	Relevant Training	Authorized for which specific discipline of Medical Testing	Part time*/full time	Specimen Signature

**in the case of part-time, mention the timing*

Annexure VI

Details of staff in the laboratory

S.No.	Name	Designation	Qualification with specialization	Relevant experience (in years) related to present work	Relevant Training	Laboratory/ Department Section	Authorized for performing which specific type of medical testing

Annexure VII

List of Equipment / Instrument

Unique ID of Equipment	Name of equipment	Make/Model	Date of place in services	Range and accuracy	Date of last calibration	Calibration due on	Calibrated by (Internal/External)

*In case of external, please specify name of calibration agency.

Annexure VIII

Details of Reference Materials available in the Laboratory

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

Annexure IX

Details of Participation in PT/ any other Inter Laboratory Comparison / EQAS

S. No.	Material to be tested	Details of test(s)/ examination	Date of testing/examination	Organizing body	Performance interms of z score or any other criteria	Corrective action taken (if required)

Note: Please submit the PT/ILC plan Annexure-I of IQAS-009 document.

Annexure X

List of Multiple location

S.No.	Name and Address of Laboratory	Name of Authorized Contact person	Phone	Email	Whether audited during the last internal audit as per ISO 15189:2022 (Yes / No)

Annexure XI

Mobile Laboratory Details

1. For Mobile Van

a. Vehicle Engine No.

b. Vehicle Chassis No.

c. Copy of Vehicle Registration Certificate (RC)

d. Vehicle Insurance Policy in force.

e. Copy of Invoice of Vehicle Purchased, in case the Vehicle is owned by the CAB.

In case of the rented vehicle, the copy of the Legally executed deed for hiring the vehicle.

2. For Movable Container (Detachable from Carrying Vehicle)

a. The identification number engraved on the Container

b. Picture/Image of the Container with engraved identification number

c. Copy of Invoice of Container Purchased, in case the Container is owned by the CAB.
In case of rented container, the copy of Legally executed deed for hiring the container.