



International Quality And Accreditation Services Pvt. Ltd.

(Formerly International Quality And Accreditation Services LLP)

307/20, 2nd Lane No. 5A, Ranjit Nagar, New Delhi 110008, India

IQAS-004

Application form for Medical Testing Laboratories

International Quality and Accreditation Services Pvt. Ltd.
(Formerly International Quality And Accreditation Services LLP)

Doc. No.: IQAS-004	Title: Application form for Medical Testing Laboratories			
Issue No.: 02	Issue Date: 01.07.2024	Amend. No.: 02	Amend. Date: 13.12.2024	Page 1 of 21



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AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of Amendment	Reasons of amendment	Amendment details	Remark	Approved by
1.	All	All	01.07.2024	Detailing	Deatiling and Rephrasing and Annexure added	Replaces earlier issue dated 20.11.2023	R.S. Rana
2.	Annexure II and III	12 & 13	02.09.2024	Detailing	Details of collection centre and POCT added	-	R.S. Rana
3.	Annexure IV to IX	12 & 13	02.09.2024	Detailing	Tables of Scope of accreditation, list of personnel for reviewing and reporting of results, list of equipment, list of reference material and list of staff are moved to annexures	-	R.S. Rana
4.	Annexure	19	02.09.2024	Outcome of APAC evaluation	PT/ILC plan is mentioned	-	R.S. Rana
5.	7	3	13.12.2024	Detailing	Addition of Medical imaging discipline	-	R.S. Rana
6.	Annexure -X to XI	20 & 21	13.12.2024	Detailing	Mobile Laboratory Details & Multiple location	-	R.S. Rana
7.	11	Annexure-I	13.12.2024	Improvement	Proprietary Firms	-	R. S. Rana

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Instructions for filling up the application.

1. The application shall be complete in all respects in the prescribed format of IQAS-004
2. The application fee and other requirements are to be referenced to the latest IQAS-001 General Information Brochure available on IQAS website, as applicable and relevant.
3. The Conformity Assessment Body (CAB) shall have adequate personnel, instruments/equipment as per the scope of accreditation along with ISO 15189:2012/2022 /relevant latest national/international or regional standards and IQAS-001 General Information Brochure guiding documents of IQAS.
4. CAB shall be a Legal Identity as per the law/rule of the Government of India.
5. CAB shall participate in ILC/PT for the applied scope.
6. 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

7. CAB shall take corrective action within the time frame specified by IQAS as mentioned in IQAS-001 General Information Brochure.
8. Terms and conditions between CAB and IQAS (IQAS -006) shall be duly signed by the CAB along with the Application Form.
9. Options opted shall be appropriately ticked by the applicant CAB in the Application Form, wherever applicable.

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1. Application Form

(Please put V 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	
2.3	Telephone	Mobile: Landline:
2.4	Email Id	
2.5	Website (if available)	
2.6	Laboratory facility	Permanent <input type="checkbox"/> Yes <input type="checkbox"/> No Site* <input type="checkbox"/> Yes <input type="checkbox"/> No Mobile* <input type="checkbox"/> Yes <input type="checkbox"/> No
		<i>*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</i>
2.7	Legal Identity registered with the government	<i>(refer Annexure I)</i>
2.7.1	Government entity <i>(Registration No. and date or Gazette Notification reference along with date)</i>	
2.7.2	Limited Liability Partnership Company <i>(Registration No. and date)</i>	
2.7.3	Private Limited Company <i>(Registration No. and date)</i>	
2.7.4	Proprietary Firm/ One Person Company <i>(Registration No. and date)</i>	
2.7.5	Partnership Firm <i>(Registration No. and date)</i>	
2.7.6	GST No. <i>(Registration No. and date)</i>	

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2.7.7	Any other Registrations which CAB desires to declare (Registration No. and date)	
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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Provide the details of multiple location in the prescribed format – Annexure X</i>
2.10	Detail of samples received	
2.10.1	Does the laboratory receive samples from sample collection centers owned by the parent company?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes: <i>Provide the details of the collection center in the prescribed format – Annexure II</i>
2.11	Point of Care Testing (POCT)	
2.11.1	Does the laboratory operate POCT?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.11.2	Is accreditation being sought for the POCT(s)	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes: <i>Provide the location(s) of the POCT in the prescribed format – Annexure III</i>
2.11.3	Is the POCT covered in the Quality Manual to monitor the accuracy and quality of POCT?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.12	Senior Management information	
2.12.1	Name of Chief Executive/Director/Head of the Laboratory.	
2.12.2	Name and designation of the person responsible for the management system	
2.12.3	Name and designation of the person responsible for technical operations	
2.12.4	Contact person for IQAS	

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	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. <i>(Attach the organization chart of the laboratory)</i>	
2.13.2	Mention how the Medical Testing laboratory is related to its parent organization. <i>(if applicable)</i>	

2. Applicable Accreditation discipline

(Please put \checkmark in the applicable box)

- | | | | | |
|--|--------------------------|-----|--------------------------|----|
| 3.1 Clinical Biochemistry | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.2 Clinical Pathology | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.3 Hematology | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.4 Microbiology and Infectious Disease Serology | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.5 Histopathology | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.6 Cytopathology | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.7 Flow Cytometry | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.8 Cytogenetics | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.9 Molecular Biology | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3.10 Medical imaging | | | | |
| a) Projection Radiography and Fluoroscopy | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| b) CT | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| c) MRI | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| d) Ultrasound and Colour Doppler | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| e) Nuclear Medicine | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| f) Interventional Radiology | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

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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 least once in the last one year Yes / No
- 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

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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 15189:2012/2022 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

Name & Designation

Date & Place

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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: 2012/22 (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 International Quality 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 CAB representative/ CAB Head / CAB Director

Name & Designation

Date & Place

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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 and PAN / Aadhar Card).
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.



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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 15189:2012/2022 (Yes / No)

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Annexure III

Details of location for POCT equipment

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

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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 15189:2012/2022 (Yes / No)

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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.