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

Medical Testing Laboratories-Application form

Instructions for filling up the application

1. The application shall be complete in all respect in the prescribed format of IQAS-004
2. The application fee and other requirements are to be referenced to the latest IQAS information/Bulletins/relevant quotation or information available on IQAS website, as applicable and relevant.
3. Conformity Assessment Body (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.
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 educational qualification and experience of CAB personnel shall be as mandated by IQAS.
7. CAB shall take corrective action within the time frame specified by IQAS.
8. IQAS terms and conditions shall be duly signed by the CAB along with the Application Form.
9. Options opted for in Application Form is to be appropriately ticked by applicant CAB.

Application Form

1. Application for getting accreditation for Medical Testing in the following category:

1.1	**New Application:**	**Yes/No**
1.2	**Renewal of existing Accreditation**	**Yes/No** **If yes :- (Earlier Accreditation certificate no…….. and validity date……..)**
1.3	**Scope addition/enhancement**	**Yes/No** **If yes :- (Earlier Accreditation certificate no…….. and validity date……..)**
1.4	**Name Change**	**Yes/No** **If yes :- (Earlier Accreditation certificate no…….. and validity date……..)**
1.5	**Premises change**	**Yes/No** **If yes :- (Earlier Accreditation certificate no…….. and validity date……..)**

2. CAB details:

2.1	**Name of the CAB**	
2.2	**Address**	
2.3	**Telephone**	**Mobile: +91** **Land line: +91**
2.4	**Email Id**	
2.5	**Website (if available)**	
2.6	**Laboratory facility:**	**Permanent Yes/No** **Site Yes/No** **Mobile Yes/No**
2.7	**Legal Identity**	
2.7.1	**Government entity (Registration No. and date or Gazette Notification reference along with date)**	
2.7.2	**Listed Limited Company (Registration No. and date)**	
2.7.3	**Private Limited Company (Registration No. and date)**	
2.7.4	**Proprietary Firm, (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 (give 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 Certificate will be issued on the name of the Legal Identity only):	
2.9	**Category of the laboratory**	
2.9.1	**Micro laboratory**	**Up to 25 patients/ day**
2.9.2	**Mini laboratory**	**26 - 50 patients/ day**
2.9.3	**Small Laboratory**	**51 - 100 patients/ day/location**
2.9.4	**Medium laboratory**	**101-400 patients/ day/location**
2.9.5	**Large laboratory**	**401-1000 patients/ day/location**
2.9.6	**Very large laboratory**	**Above 1000 patients/ day/location**
2.10	**Detail of samples received**	
2.10.1	**Sample received from various sample collection centers**	**Yes/No**
2.10.2	**Samples received from any other source**	**Yes/No**
2.11	**Senior Management information**	
2.11.1	**Chief Executive / Director / Head of the Laboratory**	
2.11.2	**Person responsible for the management system**	
2.11.3	**Person responsible for technical operations**	
2.11.4	**Contact person for IQAS**	
	Name	
	Designation	
	Contact no	
	Mobile no.	
	Landline no.	
	Email	
2.12	**Organisation Chart**	
2.12.1	**If part of larger organisation**	

	mention position of the Medical Laboratory in the organisation structure (Please also attach organisation chart of the Calibration Laboratory)	
2.12.2	**Mention how the Medical Testing laboratory is related to its own parent organization (if applicable)**	

3. Applicable Accreditation discipline

3.1	**Clinical Biochemistry**	**Yes/No**
3.2	**Clinical Pathology**	**Yes/No**
3.3	**Haematology**	**Yes/No**
3.4	**Microbiology and infectious Disease Serology**	**Yes/No**
3.5	**Histopathology**	**Yes/No**
3.6	**Cytopathology**	**Yes/No**
3.7	**Flow Cytometry**	**Yes/No**
3.8	**Cytogenetics**	**Yes/No**
3.9	**Molecular Testing**	**Yes/No**
3.10	**Clinical Biochemistry**	**Yes/No**

4. Scope of Accreditation

(Scope to be filled separately discipline wise)

Discipline: _____

Sr. No.	Product / material tested	Medical Testing method / Procedure	Range of Medical Testing/ detection limit with additional parameters	Uncertainty of Measurement (±) at Value or percentage	Permanent / site / mobile to be mentioned

5. Personnel authorised for reviewing and releasing test results

Sr. No.	CAB Department / Section	Name & Designation	Qualification with Specialisation	Relevant experience (in years) related to present work	Relevant Training	Authorized for which specific area of Medical Testing (mention part time/full time)	Specimen Signature

6. Details of staff in the laboratory

Sr. No.	Laboratory/ Department/ Section	Name & Designation	Qualification with Specialisation	Relevant experience (inyears) related to present work	Relevant Training	Responsible for performing which specific type of medical testing

7. Equipment/Instruments and CRM available in the CAB

7.1 Detail of equipment/instrument available to perform calibration

Sr. No.	Name of equipment	Model/ type/ yearof make	Receipt date& date placed in service	Range and accuracy	Date of last calibration	Calibration due on	Calibrated by

7.2 Detail of CRM available in the CAB

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

8. Internal Audit and Management Review

8.1 Date of last Internal Audit ----------

8.2 Whether all requirements of ISO/IEC 15189:2012 covering all activities of laboratory have been audited at least once in last one year. **Yes/No**

8.3 Date of last Management Review

9. Proficiency Medical Testing

Participation in PT/ any other Inter Laboratory Comparison / EQAS (please refer to ISO/ IEC 17043)

Sr. No.	Product/ Material	Details of test(s)/ examination	Date of testing / examination	Organising body	Performance in terms of z score or any other criteria	Corrective action taken (if required)

10. Application Fees

10.1 Application Fees (Rs.)……. (Amount Rs……..)

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

11. Declaration by the CAB
We declare that

11.1 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

11.2 We shall fully comply with the requirements of ISO/ IEC 17025:2017 for obtaining and maintaining the accreditation of our Calibration Laboratory.

11.3 We agree to comply with 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 assessment.

11.4 We agree to co-operate and coordinate with the assessment team appointed by IQAS for 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.

11.5 We undertake to abide all national, regional and local regulatory requirements for operating the Calibration Laboratory.

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

11.7 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

12. 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 (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)	

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

Signature of CAB representative/ CAB Head / CAB Director

Name & Designation

Date & Place