



## **APPLICATION FOR MEDICAL LABORATORY**

### **1.0 GUIDELINES FOR FILLING APPLICATION FORM**

- 1.1 Please read “Information Brochure (FDAS-100)” before filling application form.
- 1.2 Laboratories are required to state its documented management system in checklist 1, & submit along with application, available at [www.fdasindia.org](http://www.fdasindia.org).
- 1.3 Apply separately for each location.
- 1.4 Providing false information may result in rejection of the application/ termination of the accreditation process.
- 1.5 Ensure that accreditation requirements have been addressed prior to submission of the application for the applied scope.

### **2.0 Laboratories are to abide by**

- 2.1 ISO 15189:2012: General Requirements for the Competence of Medical Testing.
- 2.2 FDAS supplementary criteria for medical laboratories.
- 2.3 Terms and conditions of FDAS to maintain accreditation.
- 2.4 Terms and conditions for use of FDAS symbol.

**APPLICATION FOR MEDICAL LABORATORY**

Apply for:

<input type="checkbox"/> First assessment	<input type="checkbox"/> Reassessment
<input type="checkbox"/> Extension of Scope	

**1.0 Name of Applicant Laboratory**

.....  
.....

**1.1 Laboratory Location/ Address**

.....  
.....

Telephone No: .....Mob:-.....E-mail id:.....

**1.2 State Legal entity**

- i. Laboratory has its own legal identity.....Y/N
- ii. Laboratory is a part of large organization..... Y/N
- iii. Attach photocopy of letter issued by authority that gave legal identity.
- iv. Goods and Service Tax (GST) Number: ..... (attach copy)
- v. PAN/TAN No ..... (attach copy)

**1.3 Name of Laboratory to be written in accreditation certificate**

.....  
.....

**1.4 Name of authorized person by applicant Laboratory**

.....  
Address: .....

.....

Telephone ..... Mobile: .....

E-mail id: .....

**2.0 Other details:**

2.1 Date of commencement of Laboratory: .....

2.2 Date of compliance with current standard: .....

2.3 Is the lab open to others? Y/N

2.4 Is application for testing from permanent location? Y/N

2.5 Is application for Testing mobile facility? Y/N

2.6 Is application for site testing? Y/N

**3.0 Field of Medical Test: (Discipline)**

3.1 Clinical Biochemistry Y/N

3.2 Clinical pathology Y/N

3.3 Hematology and Immunohematology Y/N

3.4 Microbiology and Serology Y/N

3.5 Histopathology Y/N

3.6 Cytopathology

Y/N

3.7 Genetics

Y/N

3.8 Nuclear Medicine (in-vitro tests only)

Y/N

#### 4.0 Scope applied for

##### 4.1 Name of discipline: Clinical Biochemistry

S.No	Product tested	Name of test	Name the standard Test method used	Uncertainty in measurement/ Coefficient of Variation

##### 4.2 Name of discipline: Clinical Pathology

S.No	Product tested	Name of test	Name the standard Test method used	Uncertainty in measurement/ Coefficient of Variation

##### 4.3 Name of discipline: Hematology and Immunohematology

S.No	Product tested	Name of test	Name the standard Test method used	Uncertainty in measurement/ Coefficient of Variation

##### 4.4 Name of discipline: Microbiology and Serology

S.No	Product tested	Name of test	Name the standard Test method used	Uncertainty in measurement/ Coefficient of Variation

##### 4.5 Name of discipline: Histopathology

S.No	Product tested	Name of test	Name the standard Test method used	Uncertainty in Measurement/ Coefficient of Variation

**4.6 Name of discipline: Cytopathology**

S.No.	Product tested	Name of test	Name the standard Test method used	Uncertainty in measurement/ Coefficient of Variation

**4.7 Name of discipline: Genetics**

S.No	Product tested	Name of test	Name the Standard Test method used	Uncertainty in measurement/ Coefficient of Variation

**4.8 Name of discipline: Nuclear Medicine (in-vitro tests only)**

S.No	Product tested	Name of test	Name the standard Test method used	Uncertainty in measurement/ Coefficient of Variation

**5.0 Personnel details discipline wise:**

S. No	Name	Designation	Qualification	Experience (Years)

**6.0 List of equipment discipline wise:**

S. No	Name of Equipment (used as reference standard)	Make	Range

**7.0 Details of Payment of Application Fees:**

Cheque/Demand Draft/NEFT/RTGS, Number & Date	
Name of Bank & Branch	
List the field applied for	
Amount + GST	

8.0. I declare that the information furnished herewith is correct to the best of my knowledge

9.0. I am fully aware that this program involves international commitment, and to this effect I commit to abide by all norms, that are required by FDAS and any reference document which the conformity assessment body is to follow.

10.0 I, hereby give my consent on behalf of the management of the laboratory, to abide by the terms and conditions of FDAS.

Authorized Person by Applicant Laboratory

Signature with seal: .....

Name: .....

Designation: .....

Place & Date: .....



Annexure-1

**“Terms and conditions of FDAS to maintain accreditation”**

1. I, ..... Commit.
  - a. to continually fulfill the requirement for accreditation for the scope for which the accreditation is sought or granted and to commit to provide evidence of fulfilment. I, also agree to adopt to changes with the FDAS requirement of accreditation.
  - b. to cooperate as is necessary to enable the accreditation body to verify the fulfillment of the requirement for accreditation.
  - c. to provide access to conformity assessment body personnel, locations, equipment, information, documents and records as necessary to verify fulfillment of requirements for accreditation announced or unannounced.
  - d. to arrange witnessing of conformity assessment activities when requested by the FDAS.
  - e. to provide on request, access to FDAS assessment team to assess the conformity assessment body’s (Laboratory’s) at its client’s site.
  - f. to claim accreditation, only to the scope for which it has been granted.
  - g. to follow the FDAS policy for the use of accreditation symbol.
  - h. not to use its accreditation in such a manner as to bring the FDAS into disrepute.
  - i. to inform FDAS without any delay of significant changes relevant to its accreditation; like
    - its legal, commercial, ownership or organizational status.
    - organization, top management and its key personnel.
    - resources and location (s)
    - scope of accreditation
    - change in status of Authorized signatory listed with FDAS.
    - any other matter which can affect ability of laboratory to meet the requirement of accreditation.
  - j. Pay fees as determined by FDAS from time to time.
  - k. To assist in the investigation and resolution of any accreditation related complaint about the laboratory referred to it.
  - l. FDAS (Body granting accreditation) absolves itself of any legal or financial liability for any item/product calibration /tested involving accident/damage to personnel/equipment/ products at any time.
  
2. Based on the inputs received, and during the assessment if it becomes evident about submission of false information, about the resources or on evidence of its fraudulent activities, the assessment would be terminated, and the application would be rejected, or/and action would be taken as per the rules of FDAS.
  
3. I, ....., on behalf of the management agree to abide by the above Terms and Conditions of FDAS to maintain accreditation, and as a token of acceptance I am returning a dually signed copy.

Authorized Person by Applicant Laboratory

Signature with seal: .....

Name:.....

Designation:.....

Place & Date: .....



Annexure-2

**“Terms and Conditions for use of FDAS Symbol by Laboratories”**

- a) Accredited Labs shall not claim accreditation status for those test and calibrations for which they are not accredited, when it uses communication media, for any purpose.
- b) Management of accredited labs must ensure that it does nothing to mislead or make an unauthorized statement regarding its accreditation.
- c) Management of accredited lab shall not use or make any reference to accreditation upon withdrawal its accreditation, and shall discontinue display of accreditation symbol, after validity of accreditation ceases for any reason.
- d) Management of accredited lab to ensure that when needed it reproduces the accreditation symbol, exactly the same and refrain from distorting it.
- e) Management of accredited lab shall not refer to its accreditation in a way as to imply that a product, process, service, management system or person is approved by accreditation body.
- f) Management of accredited lab shall inform its affected clients of the suspension, reduction or withdrawal of its accreditation and associated consequences.
- g) Just below the Accreditation symbol of FDAS, the user lab must identify itself to indicate to which conformity activity the accreditation is related.
- h) In communication media accreditation symbol must not be used for those situations, which have not been defined or covered under the scope of accreditation.
- i) I am aware that there is provision for suitable action by FDAS, when Accreditation symbol is misused or represented, by an accredited Lab. And these could be cause for corrective action that includes publication of transgression, suspension, withdrawal of accreditation and even legal action.
- j) In that case where a lab is accredited against for more than one standard, it shall clearly identify to which conformity assessment activity the symbol refers to or is related.
- k) In case of incorrect or unauthorized claims of accreditation status including violation of any of above stated situations, FDAS would be free to take a suitable action against the concerned laboratory or the Lab, such action may include.
  - Request for corrective action
  - Suspension, withdrawal of accreditation, publication of the wrong done, and if required legal action.

I, ....., on behalf of the management agree to abide by the above terms and conditions regarding use of FDAS logo as a Symbol of Accreditation, and as a token of acceptance I am returning a dually signed copy.

Authorized Person by Applicant Laboratory

Signature with seal: .....

Name: .....

Designation: .....

Place & Date: .....