



FEDERATION FOR DEVELOPMENT OF ACCREDITATION SERVICES
118-119, First Floor, Sushant Tower, Sector 56
Gurgaon-122011, Haryana (India)

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 to submit its management system manual, checklist (as per ISO 15189), signed copy of Terms and Conditions of FDAS to maintain accreditation (FDAS 131) & Terms and conditions for use of FDAS symbol by Laboratories (FDAS 132), with its application, available at 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.
- 1.6 First time applicants are subjected to initial assessment, however on request, preliminary visit will be organized as a non-consultancy activity, to determine the preparedness of the laboratory.
- 1.7 As a policy, FDAS requires use of latest edition of test method for the scope applied.
- 1.8 Laboratories are required to enter into legally enforceable agreement for the management of all information obtained or created during the accreditation process (FDAS 138). FDAS 138 is available in website of FDAS.

2.0 Laboratories are to abide by

- 2.1 ISO 15189:2022/ISO 15189:2012* Medical Laboratories – Requirements for Quality and Competence
- 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.

*Please note, if laboratory wants Accreditation as per ISO 15189:2012, Accreditation will be valid only until December 2025 & required to be reassessed as per ISO 15189:2022 before October 2025 to ensure continuity in Accreditation.

APPLICATION FOR MEDICAL LABORATORY

Apply for:

| | |
|---|---------------------------------------|
| <input type="checkbox"/> Initial 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 identityY/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 | Material/ Product tested | Name of test | standard Test method* used | Uncertainty in measurement/ Coefficient of Variation |
|------|-----------------------------|--------------|----------------------------------|---|
| | | | | |
| | | | | |
| | | | | |

*Laboratory to provide the test method along with the year of publication

4.2 Name of discipline: Clinical Pathology

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

4.3 Name of discipline: Hematology and Immunohematology

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

4.4 Name of discipline: Microbiology and Serology

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

4.5 Name of discipline: Histopathology

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

4.6 Name of discipline: Cytopathology

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

4.7 Name of discipline: Genetics

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

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

| S.No | Material/ Product tested | Name of test | 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 | Make | Model | S.No. |
|-------|----------------------|------|-------|-------|
| | | | | |
| | | | | |
| | | | | |

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: