مركز الإمارات العالمي للاعتماد

Emirates International Accreditation Centre

طلب اعتماد

Accreditation Application for Medical Laboratory & Biobanking

EIAC-PR-02/FM-040, Rev. 5 (22-08-2023)

Date : dd-mm-yyyy

Please submit this form electronically in word and last page signed copy in pdf format to Hessa.Karim@eiac.gov.ae plus attach copy from the following documents:

☐	**Valid Legal professional, commercial, trade License** *(Please enclose proof of structure and legal status such as certificate of registration or commercial trade license registered by the relevant local authority)*
☐	**Location Map of Laboratory (Google Map or Similar GPS indices map) & Floor Plan with Major instrument location of each Section**
☐	**Signed and Stamped color scanned copy of Authorization page of this application form**

1. Applicant Information			
Organization Type:	☐ Medical Laboratory	☐ Biobanking	☐ Medical Imaging
	☐ Physiology Sciences	☐ Sample Collection Center for Medical Testing	
	☐ Others:		
Organization-name as per License			
Type of Accreditation required	☐ Initial	☐ Extension	
Criteria of accreditation	*ISO 15189: Medical Laboratory* *ISO 20387: Biobanking*		
Registered Physical Location Address			
Mailing Address			
PO Box No./ZIP Code			

City		Country	
Tel. No.		Website	
E-mail (At least 2 IDs)			
Date of Establishment		Trade license No.	

Ownership of the Organization			
• Name	***(In case of more than one person, add in a separate line)***		
• Designation			
• Mobile Phone		• Land Line Phone	
• Email			

Members of Board:	
Name the members of Board of Directors if any.	List the companies at which each member of the BOD is working in/ having shares in/having ownership of (if any)

Authorized Contact person	***(In case of more than one person, add in a separate line)***
• Name	
• Designation	
• Mobile Phone	

Working Hours			
Staff Duty Hours	☐ One Shift	☐ Two shifts	☐ Three shifts
Staff Duty Time:	From ...To ...	From ...To ...	From ...To ...

EXISTING ACCREDITATION/CERTIFICATION GRANTED TO THE ORGANIZATION				
Does Organization currently hold any accreditations/certification?		☐ Yes ☐ No If Yes, please provide the details as below:		
Accreditation Scheme (e.g. ISO 15189) Certification Scheme (e.g. ISO 9001)	Name of Accreditation Body/Certification Body	Scope of Accreditation/Certification	Certificate Number	Expiry Date of Certificate

2. INFORMATION ABOUT PROFICIENCY TESTING PARTICIPATION (Wherever Applicable) Alternate methods if PT not available			
Name of Test	Participation Date	PT Provider	Summary of results

3. PERSONNEL INFORMATION

3.1 Laboratory Director (However named)

	Laboratory Director	Deputy Laboratory Director
Name		
Designation		
Mobile No.		
E-mail		
Relevant Experience		

3.2 Quality Management Responsibility (However named). This could be more than one person.

	Quality Management Responsible	Deputy Quality Management Responsible
Name		
Designation		
Mobile No.		
E-mail		
Relevant Experience		

4. INFORMATION ABOUT INTERNAL AUDIT AND MANAGEMENT REVIEW LAST CONDUCTED DATE	
Audit Date	**MRM Date**

Note: At any point in the application process, if there is evidence of fraudulent behavior, if the CAB intentionally provides false information or if it conceals information, EIAC will reject the application or terminate assessment process

5. SCOPE OF ACCREDITATION

5.1 General Information

Laboratory/ Organization Type:	☐ Attached to Healthcare Provider facility *If yes, please select which type*	☐ Hospital Lab	☐ Clinic Lab	☐ Day Surgery Lab	
		☐ Mobile Laboratory	☐ Fertility Lab	☐ Other Specialties:	
	☐ Stand Alone				
Laboratory Category	☐ Small ≤ 75 Patient Samples per day	☐ Medium 76 to 150 Patient Samples per day	☐ Large 151 to 500 Patient Samples per day	☐ Very Large ≥ 500 Patient Samples per day	☐ Collection Centers
Authorized Signatories	As per local Health Authority Requirement				
Laboratory Disciplines	☐ Bio Chemistry & Immunology	☐ Hematology & Immuno-hematology	☐ Microbiology & Serology & Molecular Biology, Virology	☐ Histopathology & Cytopathology	☐ Genetics & Molecular & Cyto Genetics
	☐ Andrology	☐ Nuclear Medicine	☐ POCT	☐ Others: please specify	

5.2 Authorized Signatories:

#	Laboratory/ Department/ Section	Name & Designation of Signatory	Qualification with Specialization	Experience in years for Authorized area	Relevant Training, where applicable	Authorized for which specific area	Part Time / Full Time (specify timings)	Deputy Authorized Signatory

5.3 Scope: Please define the scope by filling the scope table below:

In the absence of standard specifications, documented in-house procedures may be quoted; cross-refer to your company's quality system documentation /procedures. Please indicate the test measurement technique involved wherever possible

Below is an example of what to be filled in accreditation scope:

5.3.1 Medical Scope:

#	Analytical Field/ Discipline	Type of Biological Samples	Components / Analytes	Examination Technique/Method	Examination Procedure	Equipment Name & Model
1.	Biochemistry	Serum	Glucose	Hexokinase	SOP #	Mindry 380/200, Erba XL 200 / Roche c311 /Simens Dimension-RxL
2.	Serology	Serum	HIV	Lateral flow Immunochromatography	SOP #	Roche e 411/ Beckman Access 2
3.	Microbiology	Stool	Aerobic Culture Bacterial Pathogens	Manual Culture & Automated Antibiotic Sensitivity	SOP#	Vitec 2 By Selenite F, BAP, EMB, XLD Plates and Antibiotic sensitivity

5.3.2 Biobanking Accreditation

#	Discipline	Type of Samples	Processes	Equipment Name & Model	Storage Conditions:	Methods
1.	e.g., Human samples, Animal samples Fungal samples Plant samples Microorganisms	e.g., Biofluids, cells, molecular, tissue, blood spot, hair, nails, bacteria, viruses Whole plant material, organic solvent extracts, aqueous extracts Whole material, mycelium, spores	e.g., Acquisition Collection Preparation Preservation Storage Testing/ Examination Distribution Transport Procuring Processing Receiving Tagging Accessioning/logging Packaging Cataloguing/classifying Managing Data		e.g. -80 Freezer, Slides, Cryofreeze etc.	

5.3.3 Diagnostic Imaging-Accreditation

#	Type of Activity (Radionuclide Imaging)	Type of Examination (Bone Scan/Lung Scan)	Equipment/ Techniques (Gamma Camera)	Test Procedure (SOP/Standard number)	Location (Hospital Name- Floor)
1.					

5.3.4 Physiological sciences Accreditation

#	Type of Activity /Specialization (Neurophysiology)	Type of Examination (Adult Electroencephalography EEG)	Equipment/ Techniques (XLTEK EEG/ambulatory/video telemetry recording systems)	Test Procedure (SOP/Standard number)	Location (Hospital Name- Floor)
1.	(Neurophysiology)				

5.3.5 Collection Centers:

#	Name of the collection center	Location	Operational since	Signature of in charge/responsible person

6. Needed Documents

The below documents are available and will be furnished once requested by EIAC

☐	Laboratory Management System Documents
☐	Internal Procedures (as per the accreditation criteria)
☐	Minutes/ report of last Management Review
☐	Report of last Internal Audit
☐	Participation in PT Summary where applicable & Alternate methods where applicable
☐	List of key staff and Organizational Structure
☐	Regulation/ legislation documents in the countries where CAB is located and/or offering conformity assessment services

AUTHORIZATION OF THE APPLICATION

☐ **I confirm that the information provided in this application form is true and correct.**

☐ **I acknowledge that I have read and understood and confirm to abide by the Accreditation Agreement**

☐ **I confirm that the below documents are available and will be furnished once requested by EIAC:**

☐	Laboratory Management System Documents
☐	Filled in Document Review Checklist (for 1st submission only)
☐	Internal Procedures (as per the accreditation criteria)
☐	Minutes of last Management Review Meeting
☐	Report of last Internal Audit
☐	Proficiency Test, ILC & IQC results Consolidated Data for past 6 months (for Medical Laboratory only)
☐	List of key staff and Organizational Structure if not defined in Quality Manual
☐	Medical Advisory/ Multidisciplinary Committee for POCT.
☐	Mobile Lab Sample Collection Manual

I recommend the visit to be conducted in the ☐ 1st ☐ 2nd ☐ 3rd ☐ 4th quarter of the year _____

On the behalf of the Applicant Organization:

Signed for and on behalf of Applicant	**Organization Full Name:** **_____** **Full Name of Authorized Representative:** **_____**	**Date:**
	Signature of Authorized Representative	**Designation:**
Official Stamp/Seal of Applicant		

APPLICATION REVIEW: FOR EIAC USE

Application Received Date:	Application Received by:	Reviewed by:	Date Reviewed:
Results of review:	☐ **Accept**	☐ **Reject:**	
Date of Reply to Applicant:			

Comments:

Resource Review:

Nominated Team Leader	Nominated Assessment Team Member(s)	Assessment Field	Man Days
Decision Maker(s)	**Tentative Date of Assessment according to the customer's expected date**	☐ **Yes**	
		☐ **No**	
		Alternative date:	

Reviewed by:	Date
.....	.....

Comments:

Signed for and on behalf of EIAC	Department Director Signature:	Date:
	Full Name:	