BANGLADESH ACCREDITATION BOARD (BAB)

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

APPLICATION FORM FOR MEDICAL LABORATORY ACCREDITATION

Revision 05
July 2018

AUTHOR	REVIEWER	APPROVER
Monirul Hoque Pasha Assistant Director	Md. Mahbubur Rahman Deputy Director	Md. Monwarul Islam Director General

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

Application for Medical Laboratory Accreditation to ISO 15189 *"Medical Laboratories- Requirements for quality and competence"*

Bangladesh Accreditation Board (BAB) is the National Accreditation Authority established in 2006 as an autonomous organization upgrading the quality assurance infrastructure and conformity assessment procedures in Bangladesh and enhancing the recognition and acceptance of products and services in international, regional and domestic markets. This board offers accreditation for different types of Conformity Assessment Bodies in accordance with the international principles.

1.0 Instructions:

1. This application form should be completed in full and returned with two copies of the applicant organization's Quality Manual, application fee and other related documents.
2. Bank Draft / Pay Order for the application fee should be made payable and other relevant documents submitted to:**Bangladesh Accreditation Board (BAB)**
3. Accreditation fee excluding VAT and Tax. Applicant shall pay VAT and Challan is to be submitted with payment
4. Additional information may be provided by the applicant organization on supplementary sheets, which should be clearly cross-referenced with the question numbers to which they refer.
5. Additional information may be obtained from the BAB website.
6. Award of accreditation will be subject to the applicant organization agreeing to and complying with the Accreditation Criteria, the BAB Terms and Conditions, and the other components of the BAB Contract for Accreditation. The meaning and scope of such Accreditation Criteria and Contract are defined in the BAB Terms and Conditions available on the BAB website at **http://www.bab.org.bd**
7. Please refer to relevant BAB policies, mandatory and guidance documents available from the BAB website.

For guidance on completing Application Form

Please follow the Appendix attached

BANGLADESH ACCREDITATION BOARD (BAB)

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

We apply for BAB accreditation of our Medical Testing Laboratory as per details given below:

☐ Final Accreditation ☐ Renewal of Accreditation ☐ Extension of Scope					
Pre-Assessment Requested*	Yes	☐	No	☐	

* Note that all laboratories that have never been accredited MUST undergo a pre-assessment.
(Please refer to the NOTE III & IV for details)

Section A			**General Information**
A.1	**Laboratory Details**		
	Name/ Identification of the Laboratory:		
	Location & Address:		
	Post code:		
	Telephone:		Fax:
	Mobile:		
	E-mail:		
	Laboratory's web address (optional):		
	Note: these details will be used by BAB on BAB directories, certificates etc.		

A.2	**Details of the applicant** (see appendix clause 1)		
	Name of the applicant:		
	Postal Address:		
	Post code:		
	Telephone:		Fax:
	Mobile:		
	E-mail:		
	Note: these details will be used by BAB on BAB directories, certificates etc.		

A.3	**Facility of the Laboratory** (If yes, please clearly specify in section C)	**Yes**	**No**
		Mark as X	
A. 3.1	Permanent Facility		
A. 3.2	Mobile Facility (testing undertaken at impermanent/temporary/mobile location)		
A. 3.3	Site Facility (testing undertaken at site of the customer)		

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

A.4	Category by Size (If yes, please clearly specify in section C)	Yes	No	No. of Collection units
		Mark as X		
A.4.1	Small Laboratory (up to 100 patient samples/day)			
A.4.2	Medium Laboratory (between 101 and 400 patient samples/day)			
A.4.3	Large Laboratory (between 401 and 1000 patient samples/day)			
A.4.4	Very Large Laboratory (more than 1000 patient samples/day)			

A.5	Legal status of the Laboratory	Yes	No	Registration/License/Act No. & Name of Granting authority (Evidence shall be attached)
		Mark as X		
A.5.1	Owned by an individual:			
A.5.2	Owned by a private company of partnership:			
A.5.3	Owned by a public limited company:			
A.5.4	Owned by an academic institution:			
A.5.5	Owned by a public body or nationalized industry:			
A.5.6	Another category? If so, please specify:			

A.6	Parent Organization's Details (If the laboratory is part of an organization)
A.6.1	Name & Address of Parent Organization:
A.6.2	What are the activities other than those testing subject to the application of accreditation?
A.6.3	Are they certified or accredited? (If yes, please give details)

A.7	Details of Senior Management: (name, designation, telephone, fax, email etc.)
A.7.1	Top Management (Chief Executive Officer) & Authorized Representative(s) (see appendix clause 3)
A.7.2	Laboratory Director (ref: ISO 15189 Sect. 3.9 & 4.1.1.4):
A.7.3	Person(s) responsible for technical operations (by function) (ref: ISO 15189 Sect.4.1.2.5):

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

A.7.4	Quality Manager (ref: ISO 15189 Sect. 4.1.2.7):

A.8	**Facility Contact Details -** To whom all correspondence from BAB would be made. (see appendix clause 4)	
	Name:	
	Position:	
	Address (business postal):	
	Telephone:	Fax:
	Mobile:	E-mail:

A.9	**Details of Authorized Signatories:** (see appendix clause 5)					
S.N.	Laboratory/ Department/ Section	Name & Designation of signatory (If part time/contractual basis, please indicate clearly)	Qualification with specialization	Experience in years	Relevant training	Authorized for which specific testing area

A.10	**Details of Employed Staff:**			
S.N.	Name & Designation (If part time/contractual basis, please indicate clearly)	Qualification with specialization*	Experience related to present work (in years)	Relevant training**

* Please clearly indicate the field of specialization
** Quality Manager shall have training on laboratory management system.
NOTE: Staff working in shifts shall be clearly identified

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

Section B	Equipment Information

B.1	List below the major laboratory equipment available for use (It is not necessary to list all the items, only the major equipments)					
S.N.	**Name of equipment**	**Model/ type/ year of make**	**Date of receipt and date placed in service**	**Range and accuracy**	**Date of last Calibration & Calibration by***	**Calibration Due on**

B.2	List below the Reference materials/stains/cultures available for use				
S.N.	**Name of reference material/stain/culture**	**Source**	**Date of receipt**	**Date of Expiry/validity**	**Traceability**

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

Section C					**Scope of Accreditation**
C.1	**In the table below specify as precisely as possible the scope of accreditation being sought.** ***Continue on supplementary sheets as necessary.***				
	Scope of Accreditation*				
S.N.	Type of samples to be tested (material of test)	Specific tests/examination performed	Specification against which tests performed (Standard/Method /Technique used)	Limit of its operation like (range of testing/calibration) limits of detection	Uncertainty of Measurement **(±)**
Field of testing:					
Field of testing:					

* For each field of testing use separate tables

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

Section D				Questionnaire
	It is expected that the applicant laboratory should be able to give affirmative answers to the questions. Explanation will be required for negative answers.	Yes Mark as X	No	Comment
D.1	What is the DATE of last Internal Audit?			
D.2	Whether all requirements of ISO 15189:2012 covering all activities of laboratory have been audited at least once in last one year			
D.2	Whether pre and post examination activities were included in the audit schedule			
D.4	What is the DATE of last Management Review?			
D.6	Does the laboratory participate in Proficiency testing (PT)/ External Quality Assurance (EQA)/ Inter-laboratory Comparison (ILC)?			
D.7	Does the laboratory comply with BAB PT Policy			
D.8	List below the participation in PT/EQA/ILC			

S.N	Organizing body	Test Covered (Details of test covered)	Date of testing	Performance of the laboratory

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

Section E		***Documentation Checklist***
E.1	**Application Form & Quality Manual**	
	Are TWO copies of this application forms provided? **(circle one)**	YES / NO
	Are TWO copies of the Quality Manual attached with the Application? **(circle one)**	YES / NO
E.2	**Application Fee** (Please note that BANK DRAFT/PAY ORDER is the only method for payment) (see appendix clause 6)	
	Bank Draft/Pay Order No & Date:	
	Name & Branch of the Payer Bank:	
	Bank Draft/Pay Order issued to:	Director General, Bangladesh Accreditation Board (BAB)
	Amount (in digit):	
	Amount (in words):	
E.3	**Legal Documents**	
	Registraion/ License No: If the laboratory is part of government, mention the Act under which the laboratory has been established	
	Is the Evident Document attached?	**(circle one)** YES / NO
E.4	**Scope of Accreditaiton** - All the tests are listed in section A. according to field of testing	**(circle one)** YES / NO

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

Section F	***Declaration***
We Declare that:	
F.1	We are familiar with BAB's terms & conditions for maintaining Accreditation and will abide by them
F.2	We agree to comply fully with ISO 15189:2012 for the accreditation of our medical laboratory
F.3	We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment, verification visit (if any), surveillance and reassessment irrespective of the result.
F.4	We agree to co-operate with the assessment team appointed by BAB for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of accreditation.
F.5	We satisfy all applicable national regulatory requirements for operating a laboratory.
F.6	_____ has provided consultancy for preparing the lab for BAB accreditation. (Information regarding any individual or organization who provided consultancy (if any) for BAB accreditation shall be declared)
F.7	All information provided in this application is true.

Signature of the Applicant	
Name	**Designation**
Date	

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

APPENDIX

Notes for applicants
(Please retain this section for your information)

1. Applicant

The Applicant is the owner of the facility. It may be a Department of the Government or other instrumentality, organization, company or person operating a medical laboratory or related service facility. The name shown on the application form should be the full name in which the applicant is incorporated or otherwise recognized.

2. The scope of accreditation:

In the laboratory accreditation area, for medical laboratories, BAB accreditation services currently cover the following fields:

	Fields of Accreditation
3.1)	Clinical Biochemistry
3.2)	Clinical Pathology
3.3)	Hematology
3.4)	Clinical Microbiology
3.5)	Serology and Immunology
3.6)	Histopathology
3.7)	Cytopathology
3.8)	Genetics
3.9)	Nuclear Medicine (in-vitro tests only)

NOTE:

I. **A separate application is required for each site for which you require accreditation.**
II. **BAB also offers 'corporate accreditation' covering multi-program, multi-field and/or multiple site laboratories. Special conditions apply to corporate accreditations.**
III. **Any laboratory that has been accredited by an ILAC signatory may forego the pre-assessment. Pre-assessments for such applicants is voluntary.**
IV. **Any laboratory that has never been accredited by and ILAC signatory, must undergo a pre-assessment.**

3. Authorized Representative

The Authorized Representative is the person nominated by management to represent it in all matters relating to accreditation of its facility. This person must formally accept the nomination by signing the attached Acceptance of Nomination. A facility may nominate any of its employees as its Authorized Representative but BAB recommends the appointment of an officer of appropriate seniority who has an appreciation of and an interest in the facility's activities and the standard of its performance.

A facility may nominate one person as the Authorized Representative for more than one site, or in more than one field of testing, or for more than one BAB accreditation program. Often this arrangement enhances liaison with BAB. The functions of the Authorized Representative are

91, Motijheel C/A, Dhaka-1000
Tel: +880-2-9513221
Fax: +880-2-9513222
Email: info@bab.org.bd
Web: www.bab.org.bd

distinct from those of an individual recognized by BAB for activities related to reporting or technical coordination (e.g. BAB approved signatory). The Authorized Representative may also have such responsibilities, but these are not essential for their role as the Authorized Representative.

4. Facility Contact

It is possible to list a contact person for the facility other than the Authorized Representative. The contact person is listed in the BAB Directory and in our records as the person to contact with inquiries about the facility's activities. Invoices would also be sent to this contact.

5. Authorized Signatories

Staffs who are authorized to approve and sign the test reports are authorized signatories. Authorized signatories shall demonstrate knowledge and competence commensurate with the responsibility to approve and issue results in their technical discipline.

6. Application Fee

Details of the application fees can be found in BAB's Fee Schedules, available from the BAB website.

If an initial assessment has not been conducted within twelve months of the application date and the delay has been caused primarily by the applicant, an additional application fee will be charged. If the application is still pending two years after the application date, the application will lapse.

7. Information on BAB

Before lodging an application for accreditation, you should closely examine the following documents:

a. BAB Accreditation Procedure;
b. The international standard applicable to the accreditation;
c. The application document relevant to your area of operation;
d. BAB's Terms and Condition for maintaining Accreditation.

BAB staff will be pleased to answer any questions you may have on BAB's requirements for accreditation or the processing of your application for accreditation.

8. Supporting Information

In order to process your application for accreditation, we need to know the scope of accreditation you require, and we must have current information on the staffing, accommodation, equipment and administration of your facility. This information is normally provided when you complete and return the Assessment Information Document.

9. Privacy

BAB respects and upholds the rights of individuals to privacy protection under the National Privacy Principles. A copy of BAB's Privacy Policy can be obtained from the BAB website. This policy describes how BAB manages the personal information we hold.