FORM AD 7 – MEDICAL TESTING LABORATORY ISO 15189

Objective: This form is to register an agency (company or organization), as well as to gather information and for monitoring purpose. This form does not indicate that a company is accredited under the Pusat Standard dan Akreditasi Brunei Darussalam.

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Organisation Details			
Organisation Name:			
Accreditation Body:		**Accreditation Ref No:**	

ISO 15189 MEDICAL TESTING ☐

Scope (s) Requested:

No	**MEDICAL LABORATORY FIELDS** (Activities)	**MATERIALS OR PRODUCTS TESTING** (Please list all validated/verified sample types)	**TYPES OF EXSMINATION/TECHNICAL FIELDS/ACTIVITIES** (Please provide general header and listing of all analytes/activities etc.)	**DESCRIPTION OF KEY EQUIPMENT USED, MEASUREMENT PRINCIPLE AND MAIN SOP REFERENCE**	**LOCATION[1]**
Example 1	Microbiology	Serum/heparin plasma	Therapeutic drug monitoring – antibiotics-gentamicin	Manufacturer's Analyser using Enzyme-multiplied immunoassay SOP ABC	Remote "spoke" at Medtown

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No	MEDICAL LABORATORY FIELDS (Activities)	MATERIALS OR PRODUCTS TESTING (Please list all validated/verified sample types)	TYPES OF EXSMINATION/TECHNICAL FIELDS/ACTIVITIES (Please provide general header and listing of all analytes/activities etc.)	DESCRIPTION OF KEY EQUIPMENT USED, MEASUREMENT PRINCIPLE AND MAIN SOP REFERENCE	LOCATION[1]
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					

[1] *Please indicate (with a *) on the details above any tests/ examinations/ activities that you carry out at remote sites including PoCT activities undertaken in other areas of the hospital, or in temporary or mobile facilities. Please also indicate the type of site (e.g. mobile facility) and locations.*

(To facilitate completion, the list of scopes requested can be documented on an accompanying spreadsheet or table)

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ACCREDITED CUSOMERS ONLY: PLEASE SPECIFY ANY PART(S) OF YOUR CURRENTLY ACCREDITED SCOPE THAT YOU WISH TO BE WITHDRAWN (INCLUDING METHODS BEING REPLACED BY ANY EXTENSION TO SCOPE REQUESTED ABOVE)
EXTENSIONS TO SCOPE ONLY: PLEASE PROVIDE CONTEXT TO CHANGE(S) (e.g. method change(s), additional automated platforms(s), new test(s), contractual requirement etc.)

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PLEASE IDENTIFY ANY EXTERNAL OR SUBCONTRACTED ACTIVITIES WHICH SUPPORT THE FUNCTIONING OF THE SERVICE (e.g. facilities management, procurement, HR, advisory services, etc. tighter with their location)	
ACTIVITY	**LOCATION**

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FURTHER INFORMATION (COMPLETE FOR NEW APPLICATIONS, AND WHERE RELEVANT TO AN EXTENSION TO SCOPE)	YES	NO
DOES YOUR LABORATORY MANAGE ANY BLOOD FRIDGES, PHLEBOTOMY SERVICES, BODY STORES OR MORTUARIES? (If yes please provide details below including the location)	☐	☐
DO YOU PROVIDE A SERVICE FOR ANTENATAL AND NEWBORN SCREENING PROGRAMMES (SCT, IDPS, FASP, NSB)? (If yes please provide details below)	☐	☐
DO YOU OFFER/PROVIDE ACTIVITIES OR EXAMINATION PROCEDURES THE RESULTS OF WHICH COULD BE USED AS EVIDENCE IN THE CRIMINAL JUSTICE SYSTEM? (If yes please provide details below)	☐	☐
DO STAFF PERFORM ANY EXAMINATION OR PRE-EXAMINATION ACTIVITIES OUTSIDE OF A LABORATORY SETTING (E.G. FNA ADEQUACY CHECK, MOHS SLIDE PREPARATION/EXAMINATION, SAMPLE PREPARATION AT SEXUAL HEALTH CLINIC) (If yes please provide details below)	☐	☐
INVOLVEMENT WITH RELEVANT REGULATION/INSPECTION BODIES E.G. HTA/MHRA/HSE ETC? (If yes please provide details below)	☐	☐

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FURTHER INFORMATION (COMPLETE FOR NEW APPLICATIONS, AND WHERE RELEVANT TO AN EXTENSION TO SCOPE)	YES	NO
DO YOU CONDUCT ANY MEDICAL TESTING ACTIVITIES THAT YOU DO NOT WISH TO HAVE INCLUDE WITHIN THE SCOPE OF YOUR ACCREDITATION? (If yes please provide details below)	☐	☐

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IN-HOUSE CALIBRATION:

Are there any in-house calibration(s) of equipment performed (in order to establish metrological traceability) to support any measurement activities included in your scope of application above? (Note – Information on in-house performance checks not required).

Yes ☐ No ☐

If 'yes' please provide details below

No.	MEASURED QUANTITY/ INSTRUMENT	REFERENCE STANDARD USED	PROCEDURE	PURPOSES (Detail of measurement activities that this supports)
1				
2				
3				
4				
5				
6				

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MULTI-SITE APPLICATIONS:

If your application covers activities performed at more than one site, details must be provided below. If this is an extension to scope application, please indicate if the application affects the current listing ad identified on the first page of your schedule of accreditation.

SITE No.	SITE LOCATION	ACTIVITIES PERFORMED AT THIOS SITE[2]	CONTACT DETAILS
Example	ATOWN, ASHIRE	MICROBIOLOGY PHLEBOTOMY NASAL SWAB SAMPLING	DR A, ATOWN SITE, PHONE xxxxxx
1			
2			
3			
4			
5			

[2]*Please use the same terms as referred to in the first two columns of the first table used in this form*

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EXTENSIONS TO SCOPE ONLY:

Please note the following:

- Please complete previous tables as relevant to the scope of the extension
- To enable an effective review of this application, further evidence may be requested by the Assessment Manager

Desired target grant date: _____

Desired assessment arrangements:

(Please note standard minimum BDSAC timeframe for the assessment of extensions to scope is 3 months from receipt of application, and your Assessment Manager will discuss if your chosen option doesn't fit in with your desired grant date or if your desired grant date isn't possible)

1. ☐ I wish this extension to scope application to be processed now (and understand this may require an extra visit by BDSAC).
2. ☐ I wish this extension to scope application to be processed with my text surveillance/re-assessment visit.
3. ☐ I would like to propose that this extension to scope application is considered for desktop review assessment.
   (Please note that the decision on the applicability of this proposal will be made by BDSAC based on a number of factors including existing scope of accreditation and competence demonstrated)

SUPPORTING DOCUMENTATION:

For an extension to be scope to be progressed by BDSAC the following documentation must, as a minimum, be supplied where it is applicable. Applications submitted with no supporting documentation will not be accepted.

Documentation	'Check' if supplied	Justification for non-submission
Documented technical procedure	☐	
Method verification / validation data and summary	☐	
Estimated of measurement traceability uncertainty	☐	
Detail of the measurement traceability chain	☐	
Evidence of management of the change / application of ISO 15189 requirements (e.g. change control record)	☐	
Other (Please State)		

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For an extension to be scope to be considered for desktop review assessment the following documentation, in addition to that listed above, must be supplied where applicable minimum. Applications submitted with no supporting documentation will not be accepted.

Documentation	'Check' if supplied	Justification for non-submission
Detail of Internal Quality Control including performance	☐	
EQA performance summary	☐	
Completed training/competence records of relevant staff	☐	
Record of equipment and reagents/consumables batch acceptance testing	☐	
Information for users	☐	
Example redacted reports	☐	
Other (Please State)		

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Note:

a) Each page of this form should be initialed or signed.

b) The last page of this form should include a signature with the organisation/company seal.

DECLARATION:

- I declare that I am authorized, on behalf of the generation, to submit this application, and that the information contained herein is both correct and accurate to the best of my knowledge and behalf.

Signature/Company seal:

Name:

Designation:

Date:

PLEASE SUBMIT TO:

Email: accreditation@meti.gov.bn

Tel No.: 2333964

Accreditation Unit

Pusat Standard dan Akreditasi Brunei Darussalam

Ministry of Economy, Trade and Industry
Block 19, Simpang 32-15
Bangunan Flat Kerajaan, Kampong Anggerek Desa
Mukim Berakas 'A' BB 3713
Negara Brunei Darussalam