NATIONAL TB CONTROL PROGRAMME,
BANGLADESH
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INSTRUCTION OF XPERT MTB/RIF EQA TESTING

1. Introduction of EQA item for Xpert MTB/RIF

1.1. Package specification

EQA items for Xpert MTB/RIF testing includes 5 dried-specimen tubes with label. These tubes contain inactivated *Mycobacterial* strains. Additionally, EQA items also contains 5 sterile pipettes Pasteur (3ml), 5 barcode labels for ID sample on cartridge, reporting form and ePT instruction letter.

1.2. Receipt and storage:

- Checking all of 5 tubes to ensure that there is the green color dried spot in the bottom of tube. If nothing observed, please contact to your country coordinator immediately and send the picture of the panel as an evidence.
- EQA items should be stored in dark place at room temperature (23^{o}C ± 5^{o}C) until processing the sample. After the site received the panel, **please confirm receipt of the shipment** on ePT platform **(tbept.com)**, more details in this step please refers to ePT instruction letter.

1.3. Notes:

- Open EQA panel package only accepted in laboratory performing Xpert MTB/RIF testing where bio- safety and safety precaution are available for processing with infectious specimens.
- Read carefully the instruction provided along with EQA items and follow correctly requirement
- EQA items should be processed as routine sample, not treated as special sample
- Only add sample reagents into tubes right before processing test
- During running EQA testing, just prepare adequate DTS panels for one batch, others still keep in dark place at room temperature
- If test result gets ERROR, please repeat new test using a new cartridge and treated sample within 2 hours since adding SR to have a valid result.
- EQA panel should be treated as infectious specimens.

2. Processing EQA testing

Please read SOP in page 3

3. Reporting results

Laboratories run Xpert MTB/RIF with EQA panel and **submit EQA result on ePT platform (tbept.com**) along with 05 test report pdf from GeneXpert machine as an attachment before deadline. Please refers to ePT instruction letter for more details. The your ID account and password accessing on ePT will be provided by your country coordinator in advance.

If you could not access to ePT for result submission, please send the reporting form and pdf test report via email to the **Country Coordinator** (email address country coordinator: **tanvirhuda.ntp@gmail.com**) before deadline. The subject of the email should be "<Name of Laboratory> EQA Xpert – 2022".

Name contact for technical support : Country Coordinator: Tanvir Huda, Telephone: +8801551805342, Email: tanvirhuda.ntp@gmail.com

4. How to fill in EQA report form.

Submit the result for all 5 samples:

- MTB: specify the qualification of MTB: Not Detected, Trace, Very Low, Low, Medium, High, N/A
- RIF Resistance: Detected/ Not Detected/ Indeterminate/N.A. If MTB Not Detected, fill N/A into this part.
- Cycle Threshold-Ct: take value from test report in Xpert machine (as illustrated image)

Note:

- If the result is error, please specify the code error in EQA report form.
- The lot cartridge and expired date can be found on Xpert cartridge box that used for testing

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: MTB DETECTED MEDIUM;
Rif Resistance NOT DETECTED

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	20.4	201	POS	PASS
Probe C	19.5	211	POS	PASS
Probe E	20.8	125	POS	PASS
Probe B	20.6	127	POS	PASS
SPC	26.4	274	NA	PASS
Probe A	19.3	126	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

Result			Cylce Threshold (Ct)						
ID sample	MTB (High/Medium/Low/ Very Low/Trace/ Not Detected/Error)	Rifampicin Resistance (Detected/ Not Detected/Indeterminate /N/A)	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	Performing date
			SPC	IS 1081 - IS 6110	rpoB1	rpoB2	rpoB3	rpoB4	
NTP-XPERT-22-A1	Medium	Not Detected	20.4	19.5	20.8	20.6	26.4	19.3	
NTP-XPERT-22-A2									
NTP-XPERT-22-A3									
NTP-XPERT-22-A4									
NTP-XPERT-22-A5									

5. How to save test report pdf file from Genexpert machine

- Open GeneXpert Dx System
- Click the View Results icon and then go to “Report”
- On test report window, select “Generate report file”
- On Generate report file window, select results needed to be extracted to pdf
- Save the test report file in desktop

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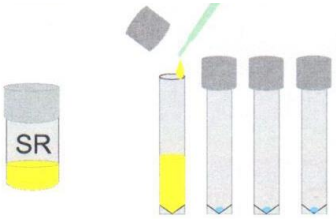
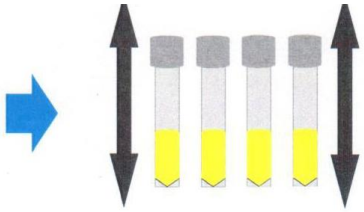
SOP FOR PROCESSING EQA SAMPLE

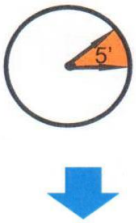
1. Using pipettes provided along with EQA items, transfer **4.5ml** sample reagent (SR) into tube. Note prepare adequate EQA samples for one batch, others still keep in dark place at room temperature



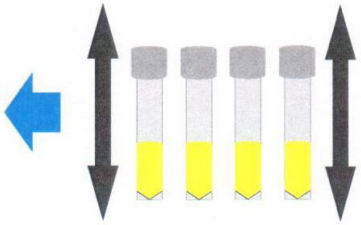
2. Tightly recap each sample after addition of SR. Shake DTS samples containing SR vigorously 10-20 times (If, dried specimens do not dissolve completely, the EQA results will be affected.



3. Incubate the sample for 5 minutes at room temperature.



4. Again shake DTS samples containing SR vigorously again 10-20 times



5. Incubate the sample for 10 minutes at room temperature

6. Using barcode label provided along with EQA items to attach on cartridge

7. Transfer 2 ml sample into cartridge, by using pipette provided in Xpert MTB/RIF kit

8. Scan ID sample's barcode and cartridge barcode

9. Load the cartridge into the GeneXpert instrument.

* To avoid the risk of cross-contamination, ensure that use one pipette for one sample and only one sample is open at a time.