**Standard Operating Procedure for Quality Testing of New Lots of Xpert MTB/RIF Reagents**

#### Introduction

Conditions during transport & storage of Xpert MTB/RIF test reagents may affect their performance. Reagent test failures could indicate that the new batch of reagents are not fit for use.

The use of positive and negative controls to monitor Xpert MTB/RIF performance is recommended for incoming QC of new batches of reagents. QC testing is done on the module that would have run the next patient sample.

#### Materials and Methods

* Positive & negative control strains:
  + Positive control (e.g., PT samples / sputum sample of know reactivity or simulated sample containing MTBC H37Rv). Dried tube specimens (preferred specimen) can be used for QC testing.
  + Negative control (e.g., PT samples / sputum sample of know reactivity or simulated sample containing *M. avium intracellulare*) or water
* Xpert MTB/RIF reagents (2 cartridges & sample reagent) from new lot
* Xpert MTB/RIF reagents (2 cartridges & sample reagent) from current lot
* MGIT 960 instrument
* Two Mycobacteria Growth Indicator Tube (MGIT) (Becton, Dickinson and Company, Sparks, Maryland)
* MGIT Growth Supplement
* Vortex
* Glass beads
* Transfer pipettes

#### Frequency of testing

Positive and negative controls should be tested with each new batch of Xpert MTB/RIF reagents received in the testing site. Testing of controls must be performed before the current batch of reagents reaches a critical low level. If this is not done, and the new batch fails QC testing, laboratories may be forced to suspend testing due to stock-outs.

#### Procedure – PT samples and sputum samples of known reactivity

1. Follow the procedure as described in the insert received with the PT panel or the Xpert MTB/RIF test processing procedure as described in the test information for use.
2. Inoculate the Xpert MTB/RIF cartridges with 1ml of the positive or negative control material.
3. Perform the Xpert MTB/RIF test and record the results*.*

#### Procedure – simulated samples

1. In the BSC, inoculate each MGIT tube (supplement added) with a control strain.
2. Incubate the MGIT tube in the MGIT instrument until the instrument indicates that the controls are positive.
3. Remove the controls from the instrument and chemical inactivate with 3 ml Xpert Sample Reagent.
4. Dilute the 1:100 control strains and disrupt any clumps by vortexing with the glass beads.
5. Inoculate the Xpert MTB/RIF cartridges with 1ml of the positive and negative controls.
6. Perform the Xpert MTB/RIF test and record the results in the new lot QC testing report form*.*

#### Interpretation of results

The interpretation of the incoming QC of new batches testing is shown below:

1. The positive control is expected to be “MTB detected”
2. The negative control is expected to be “MTB not detected”
3. Evaluate the results for both the new and current lots for both the controls. The results from positive and negative controls from new and current lots must be recorded, and unexpected results must be investigated and monitored for trends over time.
4. If new lot reagents do not produce the desired results, these reagents should not be used. Contact the manufacturer for further troubleshooting. If current lot reagents do not produce the desired results, this suggests a procedural problem. Investigate the problem and repeat the test using the new and current lots before proceeding.
5. Label kits with acceptable QC performance as “Ready for Use” or “QC passed” and receipt date.

#### New lot QC testing report form

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| **Document type: Form** | **Xpert MTB/RIF New Lot testing\_form.doc** | Place Logo here |
| **Confidentiality: None** |

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| --- | --- | --- | --- | --- | --- |
| **Xpert MTB/RIF: Current LOT** | | | | | |
| **Date tested** | **LOT**  **number** | **Positive control result:** | **Negative control result:** | **QC Pass**  **/ Fail\*** | **Initials / Comments** |
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**\*To pass QC, the positive control must be “MTB detected” and the negative control must be “MTB Not detected”.**

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| --- | --- | --- | --- | --- | --- |
| **Xpert MTB/RIF: New LOT** | | | | | |
| **Date tested** | **LOT**  **number** | **Positive control result:** | **Negative control result:** | **QC Pass**  **/ Fail\*** | **Initials / Comments** |
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**\*To pass QC, the positive control must be “MTB detected” and the negative control must be “MTB Not detected”.**

The new LOT (Lot number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_), passed / did not pass new LOT QC testing.

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Signed Date

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