

# **CONVERSION SHEET**

Xpert®
MTB/RIF
&
MTB/RIF
Ultra

# **PRODUCT COMPARISON**

| Test Reagent Kit  | Xpert® MTB/RIF*1  | Xpert® MTB/RIF Ultra*2   |
|---|---|--|
| Catalog Number  | CGXMTB/RIF-10 / GXMTB/RIF-10 (10 tests)<br>CGXMTB/RIF-50 / GXMTB/RIF-50 (50 tests)  | GXMTB/RIF-ULTRA-10 (10 tests)<br>GXMTB/RIF-ULTRA-50 (50 tests)   |
| Hands-On Time   | <1  | minute   |
| Cartridge Preparation<br>Workflow<br>(same easy process)  | 1 Add Sample Reagent to sample and incubate for 15 minutes at room temperature  2 Pipette 2 mL of inactivated sample into cartridge  3 Insert cartridge into GeneXpert® System or Infinity and start test |  |
| Sample Storage & Stability  | Sputum sediment: 2-8°C for up to 7 days<br>Unprocessed sputum: 3 days at a maximum of 35°C and 2-8°C for 4 to 10 days   |  |
| Kit Storage   | 2-28°C  |  |
| GeneXpert® Software   | GeneXpert Systems: Dx 4.0 or above<br>Infinity: Xpertise 6.1 or above   | GeneXpert Systems: Dx 4.7b or above Infinity: Xpertise 6.4b or above   |
| Reaction volume   | PCR chamber size: 25 uL   | PCR chamber size: 50 uL  |
| Turn around Time (TAT)  | 110 min   | <80 min  |
| System Throughput* (Number of tests per 8-hour shift)  * Assume 15% MTB positivity rate and average TTR of 66.8 min per test. Actual throughput may vary based on the local prevalence. | Xpert MTB/RIF Xpert MTB/RIF Ultra  16 28 64   | 320  |
| Limit Of Detection  | GX-IV<br>131 cfu/ml   | GX-XVI Infinity-80  11.8 cfu/ml  |
| MTB Detection and RIF determination   | Semi-Quantitative hemi-nested PCR Cycle threshold probe comparison  | Semi-Quantitative nested PCR High Resolution Melt technology: Better discrimination of <i>rpoB</i> mutations Silent Mutation reported as susceptible Melt temperature based analysis Detection of RIF resistance in mixed infections |
| Targets   | Detection of a single copy target:<br>rpoB gene (5 probes)  | Detection of a single copy target:  rpoB gene (4 probes)  Detection of 2 different multi-copy targets:  IS6110 & IS1081 (2 probes)   |
| Semi-Quantification   | High, Medium, Low, and Very Low   | High, Medium, Low, Very Low, and Trace <sup>^</sup> (MTB complex detected; DNA-content close to the limit of detection)  |



<sup>\*</sup> CE-IVD. In Vitro Diagnostic Medical Device. Not available in all countries. Xpert MTB/RIF is available in the United States. Xpert MTB/RIF Ultra is not available in the United States.

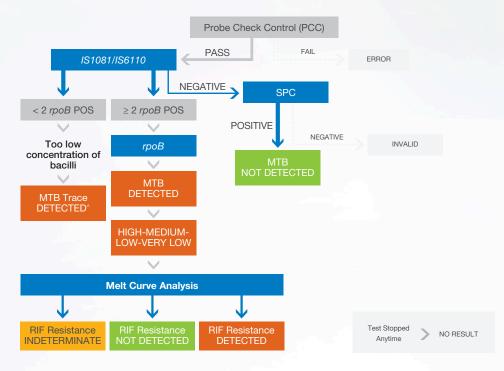
<sup>^</sup> A MTB Trace DETECTED result will be always RIF resistance indeterminate due to the low concentration of bacilli in the sample.

### **CONVERSION SHEET**

Xpert® MTB/RIF & MTB/RIF Ultra



# Interpretation of Xpert® MTB/RIF Ultra Results



Algorithm for interpretation of results: Based on the measured fluorescence signals, the Xpert MTB/RIF Ultra results for the detection of MTBC DNA and rifampicin-resistance (presence of *rpoB* gene) are calculated following the software algorithm as seen above. Each test includes a Probe Check Control (PCC) as well as Sample Processing Control (SPC) to verify that the probes and reagents are in line with the requirements needed for PCR reaction (by PCC) and if the bacteria lysis as well as PCR reaction met the validated acceptance criteria (by SPC).



## Performance of Xpert MTB/RIF Ultra

In a head-to-head comparison analysis, the overall sensitivity of Xpert MTB/RIF Ultra was 5% higher compared to the sensitivity of Xpert MTB/RIF.<sup>4</sup> The highest impact of the sensitivity increase is demonstrated among smear negative culture-positive patients (+17%) and among HIV-infected patients (+12%).<sup>4</sup> As a result of this increased sensitivity, Xpert MTB/RIF Ultra may also increase detection of non-viable bacilli particularly in patients with recent history of TB which may result in a slightly lower specificity predominantly in adult patients with pulmonary TB in high burden settings. In low burden settings, specificity of Xpert MTB/RIF Ultra is 99.3%, which can aid TB elimination efforts.<sup>4</sup>

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- ^ A MTB Trace DETECTED result will be always RIF resistance indeterminate due to the low concentration of bacilli in the sample.
- 1. Xpert MTB/RIF Package Insert 301-0191, Rev. D, November 2014
- 2. Xpert MTB/RIF Ultra Package Insert 301-5987, Rev. D, May 2017
- Jones M, et al. Xpert® MTB/RIF Ultra design and analytical performance of a second generation Xpert® MTB/RIF assay. Poster presented at ECCMID. 2016 April 9-12, Amsterdam, Netherlands
- World Health Organization. WHO Meeting Report of a Technical Expert Consultation: Non-inferiority analysis of Xpert MTB/RIF Ultra compared to Xpert MTB/RIF. Assessed
  March 2017. http://apps.who.int/iris/bitstream/10665/254792/1/WHO-HTM-TB-2017.04-eng.pdf?ua=1

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