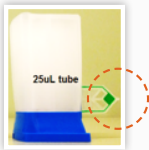
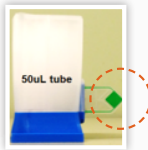
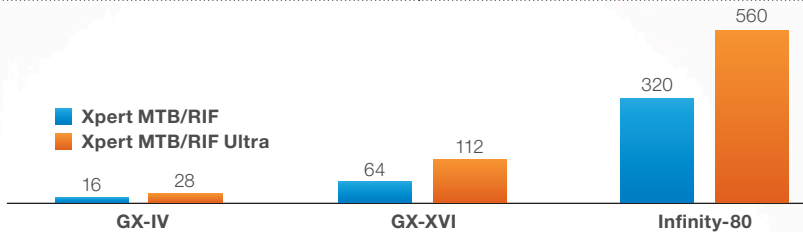




CONVERSION SHEET

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) CGXMTB/RIF-50 / GXMTB/RIF-50 (50 tests)	GXMTB/RIF-ULTRA-10 (10 tests) GXMTB/RIF-ULTRA-50 (50 tests)
Hands-On Time	<1 minute	
Cartridge Preparation Workflow (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 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 Infinity: Xpertise 6.1 or above PCR chamber size: 25 uL	GeneXpert Systems: Dx 4.7b or above Infinity: Xpertise 6.4b or above PCR chamber size: 50 uL
Reaction volume		
Turn around Time (TAT)	110 min	<80 min
System Throughput* (Number of tests per 8-hour shift)	 <p>* Assume 15% MTB positivity rate and average TTR of 66.8 min per test. Actual throughput may vary based on the local prevalence.</p>	
Limit Of Detection	131 cfu/ml	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: <i>rpoB</i> gene (5 probes)	Detection of a single copy target: <i>rpoB</i> gene (4 probes) Detection of 2 different multi-copy targets: <i>IS6110</i> & <i>IS1081</i> (2 probes)
Semi-Quantification	High, Medium, Low, and Very Low	High, Medium, Low, Very Low, and Trace [^] (MTB complex detected; DNA-content close to the limit of detection)

* 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.

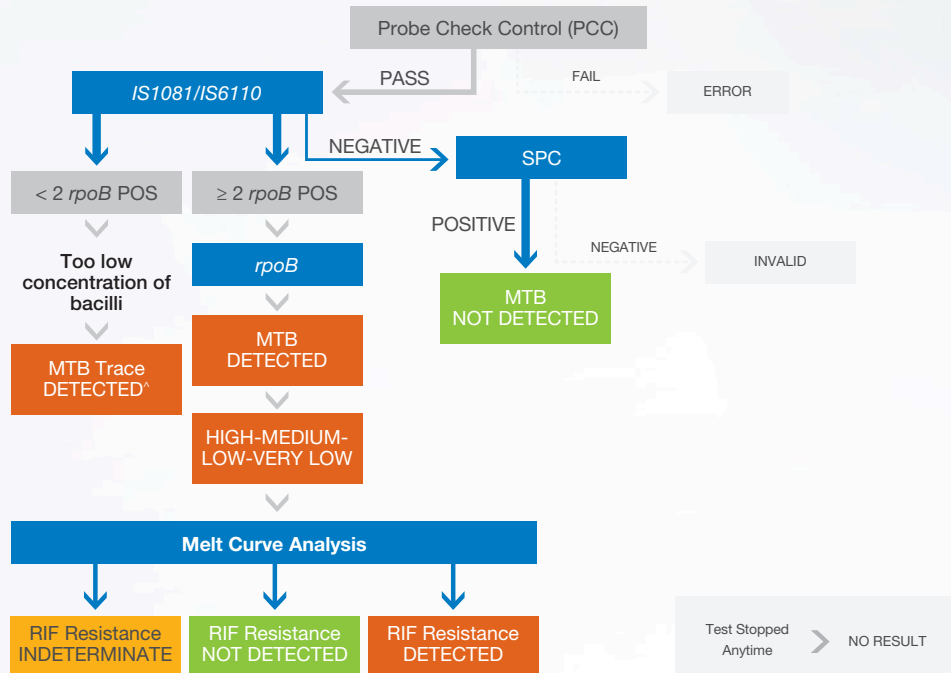
[^] A MTB Trace DETECTED result will be always RIF resistance indeterminate due to the low concentration of bacilli in the sample.

CONVERSION SHEET

Xpert®
MTB/RIF
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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.⁴ The highest impact of the sensitivity increase is demonstrated among smear negative culture-positive patients (+17%) and among HIV-infected patients (+12%).⁴ 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.⁴

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Xpert MTB/RIF is available in the United States. Xpert MTB/RIF Ultra is not available in the United States.

^ 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
3. 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
4. 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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