



<b>Test Reagent Kit</b>	Xpert MTB/RIF Ultra
<b>Catalog Number</b>	GXMTB/RIF-ULTRA-10 (10 tests) GXMTB/RIF-ULTRA-50 (50 tests)
<b>Technology</b>	Semi-Quantitative nested PCR followed by High Resolution Melt technology
<b>Targets</b>	<i>rpoB</i> gene <i>IS6110</i> & <i>IS1081</i>
<b>Batch or On-Demand</b>	On-Demand
<b>Minimum Batch Size</b>	1
<b>Sample Types</b>	Sputum sediment and unprocessed sputum
<b>Sample Extraction</b>	Automated/integrated
<b>Precision Pipetting</b>	Not Required
<b>TAT</b>	65 min for a Negative 77 min for a Positive
<b>Controls: Probe Function/Detection</b>	Probe Check Control (PCC)
<b>Controls: Process</b>	Sample Processing Control (SPC)
<b>Sensitivity*</b>	smear-positive/culture-positive: 99.5% smear-negative/culture-positive: 73.3%
<b>Specificity*</b>	95.5%
<b>Sample Storage</b>	<b>Sputum sediment:</b> 2–8 °C for up to 7 days <b>Unprocessed sputum:</b> 3 days at a maximum of 35 °C Up to additional 7 days at 2–8 °C
<b>Kit Storage</b>	2–28 °C
<b>Commercial Controls</b>	Refer to Package Inserts or Contact Cepheid Technical Support

\* The performance of Xpert MTB/RIF Ultra for detection of MTB relative to MTB culture.

CE-IVD. *In Vitro* Diagnostic Medical Device. Not available in all countries. Not available in the United States.

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