



DATASHEET

Xpert®
MTB/RIF
Ultra

XPert® MTB/RIF ULTRA

Test Reagent Kit	Xpert® MTB/RIF Ultra
Catalog Number	GXMTB/RIF-ULTRA-10 (10 tests) GXMTB/RIF-ULTRA-50 (50 tests)
Technology	Semi-Quantitative nested PCR followed by High Resolution Melt technology
Targets	<i>rpoB</i> gene <i>IS6110</i> & <i>IS1081</i>
Batch or On-Demand	On-demand
Minimum Batch Size	1
Sample Type	Sputum sediment and unprocessed sputum
Sample Extraction	Automated/Integrated
Precision Pipetting	Not required
TAT	65 min for a Negative 77 min for a Positive
Hands-On Time (sample processing, loading and starting run)	<1 minute
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control
Sensitivity*	smear-positive/culture-positive : 99.5% smear-negative/culture-positive: 73.3%
Specificity*	95.5%
Sample Storage	Sputum sediment: 2-8°C for up to 7 days Unprocessed sputum: 3 days at a maximum of 35°C Up to additional 7 days at 2-8°C
Kit Storage	2-28°C

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



In Vitro Diagnostic Medical Device

Not for distribution in the U.S.

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