

COBAS® TaqMan® MTB Test (CE-IVD)*

Enhanced workflow. Easy upgrade. Reliable results.



The COBAS® TaqMan® MTB Test utilizes the AMPLICOR® Respiratory Specimen Preparation Kit for manual specimen preparation and the COBAS® TaqMan® 48 Analyzer for automated amplification and detection.

Ease of Use with High Throughput

- Enhanced workflow with no user interaction
- 48 results in less than 2.5 hours following sample preparation

Easy Upgrade

- Compatible with COBAS® AMPLICOR® MTB Test and AMPLICOR® MTB Test sample preparation method

Test Performance

Limit of Detection

- Results from Probit analysis indicate the limit of detection for the COBAS® TaqMan® MTB Test to be 0.46 CFU/PCR or approximately 18 CFU/mL in sputum specimens.

Inclusivity

- The COBAS® TaqMan® MTB Test was evaluated with all species of Mycobacteria found in the MTB complex. 169 cultures of MTB complex species (*M. tuberculosis*: 159; *M. bovis*: 6; *M. microti*: 3; *M. africanum*: 1) were analyzed with the COBAS® TaqMan® MTB Test. One culture of *M. microti* and one culture of *M. tuberculosis* tested negative, giving an overall inclusivity rate of 99%.

The *Mycobacteria tuberculosis* (MTB) complex

<i>M. tuberculosis</i>	<i>M. microti</i>
<i>M. bovis</i>	<i>M. africanum</i>

Reliable Results

- Uses AmpErase Enzyme (uracil-N-glycosylase, UNG), a proven technology for reduced risk of contamination
- Systematic Internal Control (IC) on every sample will flag any inhibitory samples reducing the risk of reporting false negative samples
- Excellent correlation with COBAS® AMPLICOR® MTB Test

Reproducibility

- The COBAS® TaqMan® MTB Test was evaluated for reproducibility through analysis of day to day, lot to lot and operator to operator results. Of 720 results from three studies, negative results were obtained with 100% of the 132 Negative Control replicates tested. All of the 588 positive replicates, ranging from 20 to 5 copies of MTB target/PCR tested positive.

Inhibition Rate

- The rate of Invalid Internal Control results for the COBAS® TaqMan® MTB Test was determined through analysis of several studies using sputum and BAL specimens as well as panel MTB culture materials, totaling 1094 data points. The overall inhibition rate for the COBAS® TaqMan® MTB Test for all studies analyzed (specimens and MTB culture panel materials) was 0.0% (0/1094).



cobas®

Life needs answers

System Advantages



Faster Time to Results

- Fast results with an amplification/detection time of 2.5 hours for 1 to 48 sample throughput on two independent thermal cyclers.

Enhanced Workflow

- No user interaction required after sample loading is completed; no post-PCR manipulations are required

Assured Reliability

- Closed-tube format and the use of AmpErase Enzyme for state-of-the-art contamination control; full sample tracking by automated bar code reading.

Flexibility

- With a broad range of infectious and microbiology real-time PCR tests, Roche provides you with automated, flexible and customized solutions to meet the space and workflow needs of your laboratory, bringing utmost efficiency to routine molecular testing.

Connectivity

- Capability for bidirectional interfacing to laboratory information systems.

Results: Correlation between COBAS® TaqMan® MTB Test & COBAS® AMPLICOR® MTB Test

Total Sputum Results

(N = 769)

		COBAS® AMPLICOR® MTB Test		
		Positive	Negative	Total
COBAS® TaqMan® MTB Test	Positive	207	5	212
	Negative	8	549	557
Total		215	554	769

	Ratio	Percent Agreement	95% Confidence Interval
Positive % Agreement	207 / 215	96.2%	92.8 - 98.4
Negative Correlation	549 / 554	99.1%	97.9 - 99.7
Total Agreement	756 / 769	98.3%	97.1 - 99.1

BAL Results

(N = 186)

		COBAS® AMPLICOR® MTB Test		
		Positive	Negative	Total
COBAS® TaqMan® MTB Test	Positive	34	1	35
	Negative	1	150	151
Total		35	151	186

	Ratio	Percent Agreement	95% Confidence Interval
Positive % Agreement	34 / 35	97.1%	85.1 - 99.9
Negative Correlation	150 / 151	99.3%	96.4 - 99.9
Total Agreement	184 / 186	98.9%	98.9 - 99.9

For More Information

about Roche tuberculosis products, please contact the Roche Molecular Diagnostics representative in your country.

Test Ordering Information*

Product	No. of Tests	Catalog Number
COBAS® TaqMan® MTB Test (CE-IVD)	48 Tests	04803531 190
AMPLICOR® Respiratory Specimen Preparation Kit	100 Tests	20756903 122

* The COBAS® AMPLICOR® MTB and COBAS® TaqMan® MTB Tests are not available in all countries.

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