



## **COBAS® TaqMan® MTB Test (CE-IVD)\***

*Real-time PCR test for qualitative detection of  
Mycobacterium tuberculosis complex DNA*



**cobas®**

*Life needs answers*

# COBAS® TaqMan® MTB Test (CE-IVD)\*

## Real-time PCR test for qualitative detection of *Mycobacterium tuberculosis* complex DNA

**Tuberculosis (TB) is a contagious disease caused** by *Mycobacterium tuberculosis* which if left untreated can lead to serious complications, including death. Like the common cold, it spreads through the air. Only people with active lung disease are infectious. When infectious people cough, sneeze, talk or spit, they propel TB germs into the air. A person needs only to inhale a small number of these to be infected. Overall, one-third of the world's population is currently infected with the TB bacillus. Of the people who are infected with TB bacilli, 5-10% become sick or infectious at some time during their life. It is estimated that 1.7 million deaths resulted from TB in 2004. As with cases of disease, the highest number of estimated deaths is in the South-East Asia Region,

but the highest mortality per capita is in the Africa Region, where HIV has led to rapid increases in the incidence of TB and increases in the likelihood of dying from TB. WHO targets, ratified by the World Health Assembly in 1991, are to detect 70% of new infectious TB cases and to cure 85% of those detected by 2005. Eighteen countries had already achieved these targets in 2002.<sup>1-5</sup>

**Due to the risk of the spread of the disease, the potential for the emergence of drug-resistant strains, and the severity of the disease in patients infected with HIV-1, the rapid diagnosis of the *M. tuberculosis* complex is extremely important.**

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### The COBAS® TaqMan® MTB Test

#### Faster Time to Results

The COBAS® TaqMan® MTB Test offers up to 48 tests per run and provides results in only 2.5 hours after sample preparation.



#### Real-time PCR Testing

Conventional testing methods for *Mycobacterium tuberculosis* require isolation of the organism and can take up to eight weeks for a definitive result.

In contrast to more labor-intensive NAT tests, the COBAS® TaqMan® MTB Test offers up to 48 tests per run and provides results in only 2.5 hours after sample preparation. The test is run on the COBAS® TaqMan® 48 Analyzer, which offers automated amplification and detection in a closed system. Systematic Internal Control for each test helps enhance quality control in your lab.

#### Intended Use

The COBAS® TaqMan® MTB Test is an in vitro nucleic acid amplification test for the qualitative detection of *Mycobacteria tuberculosis* (MTB) complex DNA in liquefied, decontaminated and concentrated human respiratory specimens, including sputum and bronchial alveolar lavages. The test utilizes the AMPLICOR® Respiratory Specimen Preparation Kit for manual specimen preparation and the COBAS® TaqMan® 48 Analyzer for automated amplification and detection.

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### Comprehensive Solutions

Roche offers a comprehensive set of products, services and technologies designed to help laboratories successfully streamline their workflow, optimize throughput and provide reliable data faster for more actionable healthcare.

#### AMPLILINK Software

AMPLILINK software is a Windows®-based system that manages the operation of the connected COBAS® instruments and analyzers. Configuration management tools let you customize functionality to optimize:

#### Result Integrity & Data Security

- Full sample tracking by automated bar code reading

#### Flexibility

- Integrated sample processing and detection systems
- Multiple system management, including system maintenance and sample and reagent level

#### Simplicity

- Easy-to-read graphic display of samples status

#### Connectivity

- Capability for bidirectional interfacing to laboratory information systems

## Improved Workflow, Reliable Results

The COBAS® TaqMan® 48 Analyzer helps increase your laboratory's capability and productivity with automated amplification and detection of DNA or RNA. A real-time PCR qualitative test provides superior assay performance, with broad dynamic ranges and excellent sensitivity and specificity.

### Faster Time to Results

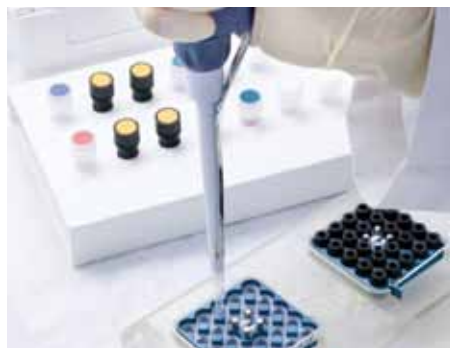
- Two independent thermal cyclers in one instrument provides 1 to 48 sample capacity and results in less than 2.5 hours
- No user interaction or post-PCR manipulations required after sample loading

### Multiple Layers of Contamination Control

- Closed-tube format and the use of AmpErase Enzyme (uracil-N-glycosylase, UNG) for state-of-the-art contamination control
- Systematic Internal Control on every sample will flag any inhibitory samples reducing the risk of reporting false negative sample

### Easy Upgrade

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



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

### Total Sputum Results (N = 769)

		COBAS® AMPLICOR® MTB Test		Total
		Positive	Negative	
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

**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*	48 Tests	04803531 190
AMPLICOR® Respiratory Specimen Preparation Kit	100 Tests	20756903 122

### Available Assays that Run on this Platform

Test Kit*	Catalog Number
COBAS® Taqman® CT Test (CE-IVD)	04341341 190
COBAS® AmpliPrep/COBAS® TaqMan® HBV Test (CE-IVD)	03587819 190
COBAS® AmpliPrep/COBAS® TaqMan® HCV Test (CE-IVD)	03568547 190
COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test (CE-IVD)	03543005 190
COBAS® TaqMan® HBV Test For use with the High Pure System (CE-IVD)	03500756 190
COBAS® TaqMan® HCV Test, v2.0 For use with the High Pure System (CE-IVD)	04861817 190
COBAS® TaqMan® HIV-1 Test For use with the High Pure System (CE-IVD)	03501752 190

\* These products are not available in all countries.

#### Footnotes

- <sup>1</sup> World Health Organization Fact Sheet N° 104 Revised April 2005
- <sup>2</sup> Tuberculosis Elimination Revisited: Obstacles, Opportunities, and a Renewed Commitment—Advisory Council for the Elimination of Tuberculosis (ACET). Morbidity and Mortality Weekly Reports 1999. (RR09); 1-13.
- <sup>3</sup> Metchock, B.G., Nolte, F.S. and Wallace, R.J. 1999. Mycobacterium, pp. 339-437. In: Manual of Clinical Microbiology, 7th ed., eds. Murray, P.R., Baron, E.J., Tenover, M.C., Tenover, F.C. American Society for Microbiology, Washington, D.C.
- <sup>4</sup> Bloom, B.R. and Murray, C.J.L. 1992. Tuberculosis: commentary on a re-emergent killer. Science 257:1055-1063.
- <sup>5</sup> Böttger, E.C. 1991. Detection, differentiation, and systematics of bacterial pathogens - the family Mycobacteriaceae. Immunitat und Infektion 19:143-152.

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