



COSARA
DIAGNOSTICS
PVT. LTD

SARAGENE™ Mycobacterium Tuberculosis Real-Time PCR test

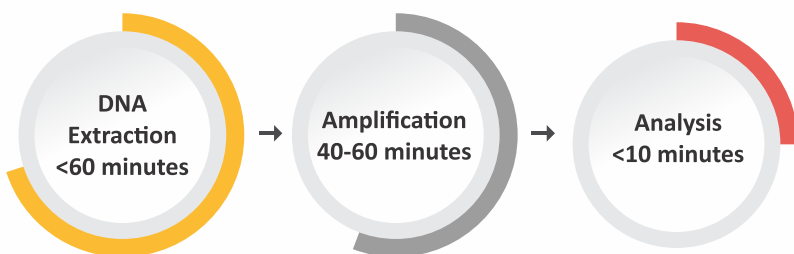


MTB Real-time PCR Test Information

The MTB assay is a Real-Time PCR (RT-PCR) test used to detect the presence or absence of *IS6110* and *MPB64* genes from tuberculosis complex members including Mycobacterium species *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. canetti*, *M. microti* and *M. pinnipedii* from extracted deoxyribonucleic acid (DNA). RT-PCR is more sensitive than smear microscopy, faster than culture and is now cost-effective, making it the preferred global solution for rapid, accurate and inexpensive detection of tuberculosis.

Results within two hours

The MTB tests can be performed in less than two hours. The test requires a clean, contamination free environment with a hood, centrifuge, pipettes and RT-PCR machine. The test is compatible with most RT-PCR devices with green, yellow and orange channels and it can be customized to work with a myriad dyes and PCR technologies.



MTB RT-PCR KIT

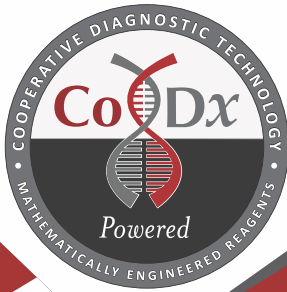
- Compatible with multiple sample types, platforms and sample extractions
- Simple and streamlined workflow
- Includes internal control to verify sample quality
- Includes positive control
- Produces results that are easy to interpret

IVD



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Sensitive, Fast and Affordable Molecular Diagnostics
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SARAGENE™ MTB

Real-Time PCR Test Specifications

About CoDx™ Technology

The MTB kit is developed using a revolutionary molecular diagnostics technology called CoPrimers™, a technology invented and patented by Co-Diagnostics, Inc (Utah, USA).

CoDx technology is mathematically engineered to enhance the speed, accuracy, and cost-effectiveness of RT-PCR. The technology is based on cooperative theory, a mathematical model developed by Brent Satterfield, Ph.D. This model applies advanced algorithms and bioinformatics to optimize design parameters with analyte targets. In comparison with other technologies, the CoPrimers reduce the formation of primer-dimers, increase specificity and increase ability to multiplex. The Journal of Molecular Diagnostics (March 2014) introduced CoPrimers as a “new class of primer technology that greatly reduces primer-dimer propagation, showing a 2.5 million-fold improvement in reduction of nonspecific amplification.”

Application	Qualitative RT-PCR													
Sample type	Pulmonary and extra pulmonary samples													
Type of detection	Presence or absence of <i>IS6110</i> and/or <i>MPB64</i>													
Specificity	<i>Mycobacteria tuberculosis</i> complex members including <i>M. tuberculosis</i> , <i>M. bovis</i> , <i>M. africanum</i> , <i>M. canetti</i> , <i>M. microti</i> and <i>M. pinnipedii</i>													
Limit of Detection	<table border="1"> <thead> <tr> <th>Gene Marker</th> <th>Mycobacteria species</th> <th>Limit of Detection (copies/μL)</th> </tr> </thead> <tbody> <tr> <td rowspan="2">IS6110</td> <td><i>M. tuberculosis</i></td> <td>2.0x10³</td> </tr> <tr> <td><i>M. africanum</i></td> <td>2.0x10³</td> </tr> <tr> <td rowspan="2">MPB64</td> <td><i>M. tuberculosis</i></td> <td>8.0x10³</td> </tr> <tr> <td><i>M. africanum</i></td> <td>8.0x10³</td> </tr> </tbody> </table>	Gene Marker	Mycobacteria species	Limit of Detection (copies/μL)	IS6110	<i>M. tuberculosis</i>	2.0x10 ³	<i>M. africanum</i>	2.0x10 ³	MPB64	<i>M. tuberculosis</i>	8.0x10 ³	<i>M. africanum</i>	8.0x10 ³
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	<i>M. africanum</i>	8.0x10 ³												
Thermal cycler compatibility	Most RT-PCR systems with the following channel compatibilities: Green (FAM), Yellow (CAL Fluor® Orange 560), and Orange (CAL Fluor® Red 610)													

MTB Kit Includes

MM	Master Mix
PC	Positive Control
NC	Negative Control

Ordering Information

Product Name	Number of Reaction
SARAGENE™ MTB RT PCR KIT	25 RxS
	50 RxS
	100 RxS

* RT PCR machine available on request

The performance of the MTB RT-PCR Test has been evaluated for precision, accuracy, sensitivity and specificity for relevant *M. tuberculosis* complex members.

Intended Use: For Detection of Tuberculosis



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