



Co-Dx Logix Smart™ MTB

Innovating Molecular Diagnostic Solutions

Co-Dx Logix Smart™ MTB is a real-time CE-IVD PCR test used to detect the presence or absence of Mycobacterium tuberculosis complex members, including *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. canetti*, *M. microti*, and *M. pinnipedii* through detection of the IS6110 and MPB64 genes from extracted deoxyribonucleic acid (DNA) from respiratory tract specimens.

Logix Smart™ MTB has been validated with the QIAamp DNA Mini (QIAGEN) extraction kit and run in the Co-Dx Box™ thermal cycler.

About Co-Dx Logix Smart™ MTB

The performance data of Logix Smart™ MTB was evaluated for precision, limit of detection, diagnostic accuracy, and analytical specificity for relevant Mycobacterium tuberculosis complex microorganisms including *M. bovis*, *M. africanum*, *M. microti*, *M. caprae*, and *M. pinnipedi*. Logix Smart™ MTB was capable of detecting all relevant tested MTB-complex microorganisms. The specificity was tested to exclude cross-reactivity with other relevant mycobacterium, like *M. avium*, *M. kansasii*, and *M. intracellulare* in wet-tests. Logix Smart™ MTB did not cross-react with a panel of 30 microorganisms, as described in the technical file, or against most relevant drugs used in treatment that could possibly interfere in the results including Rifampicin, Isoniazid, Pyrazinamide, Ethambutol, and Streptomycin.

Co-Dx Logix Smart™ MTB

- Compatible with multiple sample types
- Contains a simple and streamlined work flow
- Includes internal control to verify sample quality
- Includes positive control
- Produces results that are easy to interpret
- Compatible with multiple platforms & sample extraction techniques



Product Performance Characteristics

Application	Qualitative PCR test, screening		
	Marker	Mycobacterium	Claimed LOD
Limit of detection	IS6110	M. tuberculosis	2.0×10 ³ copies/mL
		M. africanum	2.0×10 ³ copies/mL
	MPB64	M. tuberculosis	8.0×10 ³ copies/mL
		M. africanum	8.0×10 ³ copies/mL
Diagnostic sensitivity	98%† IS6110 & 100%† MPB64		
Diagnostic Specificity	99%† IS6110 & 99.6%† MPB64		
Sample type	Sputum and extra-pulmonary samples		
Genotype detection	None		
Multi-drug resistance	None		
Detection details	Presence/absence of the IS6110 and MPB64 genes from mycobacterium tuberculosis complex members, including the following Mycobacterium species: M. tuberculosis, M.bovis, M. africanum, M. canetti, M. microti, M. pinnipedii		
Time to detection	45-66 minutes, depending on the machine used		
Thermal cycler compatibility	Most qPCR systems capable of the following channel compatibilities: FAM CF560 (VIC) CF610(ROX)		

† Results based on 556 contrived samples extracted using QIAamp DNA Mini kits and run on the CoDx Box™.

Each Co-Dx Logix Smart™ MTB kit includes:

- 1×500 µL (100rxns) Logix Smart™ MTB Master Mix
- 1×500 µL (100rxns) Logix Smart™ MTB Positive Control
- 1×500 µL (100rxns) Nuclease Free Water

Ordering Information:

Product Name	Product ID
Co-Dx Box™ Thermal Cycler	Request quote
Co-Dx Logix Smart™ MTB kit	MTB-K-007