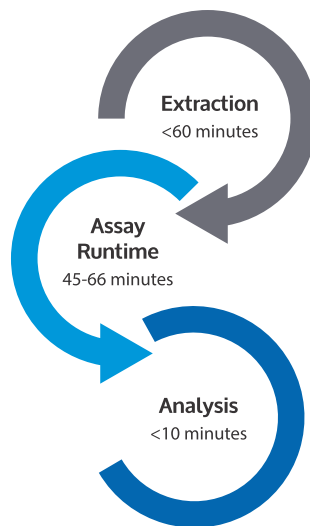


Logix Smart™ MTB

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 QIAamp DNA Mini (QIAGEN) extraction kit and run using the CoDx Box™ Thermal Cycler.



- 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



Logix Smart™ MTB

The performance of the Logix Smart™ MTB test kit was evaluated for precision, limit of detection, diagnostic accuracy, and analytical specificity testing 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. Exclusivity testing was also performed with other relevant non-tuberculosis causing 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, cross-reactivity for most relevant drugs used in treatment that could possibly interfere in the results including Rifampicin, Isoniazid, Pyrazinamide, Ethambutol, and Streptomycin.

Product Performance Characteristics

Application	Qualitative PCR test, screening		
Limit of detection	Marker	Mycobacterium	Claimed LOD
	IS6110	<i>M. tuberculosis</i>	2.0x10 ³ copies/mL
		<i>M. africanum</i>	2.0x10 ³ copies/mL
	MPB64	<i>M. tuberculosis</i>	8.0x10 ³ copies/mL
		<i>M. africanum</i>	8.0x10 ³ copies/mL
Diagnostic Sensitivity	98%† IS6110 & 100%† MPB64		
Diagnostic Specificity	99%† IS6110 & 99.6%† MPB64		
Sample type	Sputum and respiratory 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: <i>M. tuberculosis</i> , <i>M. bovis</i> , <i>M. africanum</i> , <i>M. canetti</i> , <i>M. microti</i> , <i>M. pinnipedi</i>		
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 Logix Smart™ MTB kit includes:

- 1x500µL (100rxns) Logix Smart™ MTB Master Mix
- 1x500µL (100rxns) Logix Smart™ MTB Positive Control
- 1x500µL (100rxns) Nuclease Free Water

Ordering Information:

Product Name	Product ID
CoDx Box™ Thermal Cycler	Request Quote
Logix Smart™ MTB kit	MTB-K-007