



Quality Controls for *Mycobacterium tuberculosis* (MTB) Testing

Tuberculosis (TB) is a contagious bacterial infection caused by *Mycobacterium tuberculosis* that primarily affects the lungs and can spread to other organs. It is an airborne disease characterized by two stages: a latent phase where the bacteria remain dormant and an active phase where symptoms like persistent cough, chest pain, and fatigue occur. Early and accurate screening not only enables timely treatment but also identifies drug-resistant strains, allowing clinicians to choose the most effective therapy and reduce the risk of transmission.

NON-INFECTIOUS



Consist of non-infectious, synthetic MTB DNA encapsulated in chemically fixed bacteria cells, providing a safe and robust alternative for lab use



ESSENTIAL TOOL

Help ensure that results are accurate, reliable, and clinically meaningful, which is critical for a disease with serious public health implications

MUTATION COVERAGE



Include drug-resistance mutations, wild-type strains, and true negative controls ensuring accurate screening and helping to prevent false positives



FULL MONITORING

Designed to monitor the entire molecular testing process, including extraction, amplification, and detection steps

Tuberculosis Controls

Unassayed Tuberculosis Controls

INTROL® TB Panel M110

Catalog No.: M110 Kit Contains 4 bottles total: 1 bottle each of TBWT-04, TBMDR1-04, TBMDR2-04, & TBNEG x 3 mL

- Tested and compatible with:
- Xpert® MTB/RIF assay (Cepheid)
 - INNO-LiPA Rif.TB assay (Innogenetics)
 - GenoType® MTBDRplus assay (Hain Lifescience)

Consult with MMQCI for compatibility with other test methods.

Assayed Tuberculosis Controls

INTROL® TB Panel M114

Catalog No.: M114-5 Kit Contains 15 bottles total: 5 bottles each of TBWT-04, TBMDR1-04, & TBNEG x 1 mL

Catalog No.: M114-10 Kit Contains 30 bottles total: 10 bottles each of TBWT-04, TBMDR1-04, & TBNEG x 1 mL

Designed for the Xpert® MTB/RIF assay (Cepheid)

INTROL® TB Panel M114plus

Catalog No.: M114plus Kit Contains 12 bottles total: 3 bottles each of TBWT-04, TBMDR1-04, TB1081MDR2, & TBNEG x 1 mL

Designed for the Xpert® MTB/RIF assay (Cepheid)

INTROL® TBNEG-30

Catalog No.: M115 Kit Contains 30 bottles of TBNEG x 1 mL

Designed for the Xpert® MTB/RIF assay (Cepheid)

INTROL® TB-XDR Panel M345

Catalog No.: M345-5 Kit contains 15 bottles total: 5 bottles each of TB-XDR WT, TB-XDR MUT, & TB-XDR NEG x 1 mL

Designed for the Xpert® MTB/XDR assay (Cepheid)

Drug Resistance Mutations

Control	Drug Resistance Mutation	M110	M114	M114plus	M115	M345
INTROL TBWT-04	Wild Type (H37Rv)	✓	✓	✓		
INTROL TBMDR1-04	rpoB: F505L, L511P, D516V, H526Y inhA: -15 katG: S315T (AGC > ACC)	✓	✓	✓		
INTROL TBMDR2-04	rpoB: S522L, H526D, S531L inhA: -8 katG: S315T (AGC > ACC)	✓				
INTROL TB1081MDR2	rpoB: S522L, H526D, S531L inhA: -8T > C			✓		
INTROL TBNEG	No MTB DNA, no cells	✓	✓	✓	✓	
INTROL TB-XDR WT	Wild Type					✓
INTROL TB-XDR MUT	eis promoter (-14 C > T), fabG1: L203L (CTg>CTa), gyrA: D94G (Gac > GgC), gyrB: E540D (GAa > GAc), inhA promoter: (-15 C > T), katG: S315T (AgC > AcC), oxyR-ahpC (-39 C > T) and rrs (a1401g)					✓
INTROL TB-XDR NEG	No MTB DNA, no cells					✓

Maine Molecular Quality Controls, Inc. | 23 Mill Brook Road, Saco, ME 04072, USA