INTROL® TB PANEL M110

INTENDED USE:

INTROL® TB Panel M110 is intended for use as a quality control to monitor analytical performance of the extraction, amplification and detection steps of *M. tuberculosis* (MTB) molecular assays. INTROL™ TB Panel M110 is formulated for use with *in vitro* assays that detect the presence of MTB and multi-drug resistant MTB (MDR-TB) mutations.

The World Health Organization (WHO) reports that about 1.7 billion people, 23% of the world's population, are estimated to have a latent TB infection, and are thus at risk of developing active TB disease during their lifetime.[1] There has been major progress in subsequent years – more than 60 million people have been documented as treated and cured since 2000, and case and death rates have fallen steadily. Nevertheless, worldwide, around 10 million people still fall ill with the disease each year (more adults than children, and more men than women), and TB is one of the top 10 causes of death. It is also the leading cause of death from a single infectious agent, ranking above HIV/AIDS. [2]

INTROL® TB Panel M110 is provided for Research Use Only (RUO). It cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

PRODUCT SUMMARY and PRINCIPLE:

INTROL® TBWT-04, TBMDR1-04 and TBMDR2-04 of TB Panel M110 consist of non-infectious, synthetic MTB DNA encapsulated in chemically fixed and killed bacterial cells. The MTB DNA does not include the entire MTB genome but is comprised of the following MTB gene segments: IS6110, hsp65, 16S rRNA, 23S rRNA, inhA, katG, and rpoB. Drug resistance mutations are incorporated in segments inhA, katG, and rpoB, as indicated in Table 1. The controls must be extracted to effectively release the MTB DNA from the cells. INTROL® TBWT-04, TBMDR1-04 and TBMDR2-04 test positive in Xpert® MTB/RIF (Cepheid), INNO-LiPA Rif.TB (Innogenetics) and GenoType® MTBDRplus (Hain Lifescience) assays. Consult with MMQCI for compatibility with other test methods.

Best practice is to establish a quality control program for every assay performed by the laboratory.[3, 4] Routine use of quality controls that are consistent lot to lot and monitor the entire assay assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents and pipetting errors. Early investigation can prevent failed assay runs.

COMPOSITION:

INTROL® TB Panel M110 is comprised of four bottles, 3 mL each. Three bottles contain encapsulated MTB DNA, gene segments IS6110, hsp65, 16S rRNA, 23S rRNA, inhA, katG, and rpoB. The fourth bottle contains buffer and preservative only. The cells encapsulating the MTB DNA are suspended in buffer with preservative. The presence or absence of drug resistance mutations is specified for each bottle in Table 1.

Table 1. Drug Resistance Mutations* found in INTROL® TB Panel M110

Control	Drug Resistance Mutation
INTROL® TBWT-04	no mutations/ wildtype (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>ACA)
INTROL® TBNEG	No MTB DNA, no cells

*References citing the mutations can be found at www.tbdreamdb.com.

INTROL® TB Panel M110 controls do not have assigned concentrations. DNA yield will depend on individual laboratory's extraction and test methods.

PRECAUTIONS AND WARNINGS:

INTROL® TB Panel M110 is provided for Research Use Only (RUO), not for use in diagnostic procedures. It cannot be cloned, sold, or transferred without the explicit written consent of MMQCI. This product does not contain any biological material of human origin or infectious microorganisms. Do not freeze.

STORAGE and STABILITY:

Upon receipt and after opening, the material should be stored at 2° – 8°C. Do not freeze.
Unopened controls are stable through the expiration date printed on each bottle when stored at 2° – 8°C. Opened material tightly capped and returned to the refrigerator (2° – 8°C) shortly after use is stable for thirty (30) days from the date of opening.

INSTRUCTIONS FOR USE:

1. Allow controls to come to room temperature (18° – 25°C).
2. Thoroughly mix controls by vigorously inverting several times and pulse vortexing immediately before use.
3. Before opening bottle, shake down or tap bottle on hard surface to be sure all liquid is out of cap.
4. Process a minimum of 0.5 mL of each control and test according to manufacturer's instructions.
5. Some test methods may require concentration of controls by centrifugation before extraction. Concentrate 0.5-1.0 mL of each control according to manufacturer's instructions. The control pellet may not be visible; therefore the 'up' side of the tube should be marked as it goes into the centrifuge. Best results are obtained if some supernatant is left on the pellet in order to prevent disturbance of the pellet when supernatant is removed.

Procedural Note:
1. Extracted control DNA is not quantifiable by spectrophotometer methods.

LIMITATIONS:

INTROL® TB Panel M110 is designed for use with MTB amplification assays that target one or more of the following MTB gene segments: hsp65, rpoB, 16S rRNA, 23S rRNA, inhA, katG, and IS6110. Only those segments are present in INTROL® TB Panel M110.

EXPECTED VALUES:

INTROL® TB Panel M110 does not have assigned values. The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for INTROL® TB Panel M110 by analyzing data from multiple runs. Recoveries may vary depending on extraction method, probes and primers, instrumentation, cycle time / temperature, reagents, method variation, and other systematic or random errors.

REFERENCES:

1. WHO report 2018: https://www.who.int/tb/publications/global_report/en/
2. "Ten Facts About Tuberculosis," WHO, September 2018: http://www.who.int/features/factfiles/tuberculosis/en/index.html
3. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
4. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000

ORDERING INFORMATION:

INTROL® TB Panel M110
Part Number: M110
Kit Contains: 4 bottles x 3mL