

## INTROL™ TBNEG-30 INSTRUCTIONS FOR USE

### INTENDED USE:

INTROL™ TBNEG-30 is intended for use as a quality control to monitor analytical performance of *M. tuberculosis* (MTB) on the GeneXpert® System. INTROL™ TBNEG-30 is formulated to monitor the detection of MTB and multi-drug resistant MTB (MDR-TB) mutations.

The World Health Organization (WHO) reports that one-third of the world's population is infected with MTB.<sup>1</sup> In 2009, 1.7 million people died from tuberculosis (TB) and 9.4 million new cases were reported. MDR-TB is increasing with some regions reporting as much as 28% of new TB cases are MDR-TB.<sup>2</sup>

INTROL™ TBNEG-30 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™ TBNEG-30 is comprised of 30 bottles containing buffer and preservative only.

Best practice is to establish a quality control program for every assay performed by the laboratory.<sup>3,4</sup> 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™ TBNEG-30 is comprised of 30 bottles, 1 mL each, containing buffer and preservative only, no MTB DNA, no cells.

### PRECAUTIONS AND WARNINGS:

INTROL™ TBNEG-30 is for use on the GeneXpert® System only. 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. Each bottle is for single use. Discard after use according to your local and federal regulations.

### INSTRUCTIONS FOR USE ON THE GeneXpert® System:

1. Each bottle contains 1.0mL of control material.
2. Allow controls to come to room temperature.
3. Thoroughly mix controls by vigorously inverting several times immediately before use.
4. Before opening bottle, shake down or tap bottle on hard surface to be sure all liquid is out of cap.
5. Add 2 mL Sample Reagent to each control vial.
6. Mix by inverting the vial 10 times.
7. Let the vial sit at room temperature for 15 minutes. Invert several times half way through incubation period as you would for a sputum sample.
8. Open the Xpert® MTB/RIF cartridge lid and transfer 2.0 mL of respective Sample Reagent treated control, using a sterile transfer pipette. Close lid.
9. Transfer cartridge to the GeneXpert system.
10. Scan cartridge, enter sample ID and start the run.

### LIMITATIONS:

INTROL™ TBNEG-30 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.

### EXPECTED VALUES:

Control	Xpert MTB/RIF Expected result
INTROL™ TBNEG	MTB NOT DETECTED

### REFERENCES:

1. "Ten Facts About Tuberculosis," WHO, November 2010: <http://www.who.int/features/factfiles/tuberculosis/en/index.html>
2. WHO report 2010: [http://www.who.int/tb/publications/global\\_report/2010](http://www.who.int/tb/publications/global_report/2010).
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™ TBNEG-30

**Order Number: M115**

Contains: 30 TBNEG bottles, 1 milliliter each