Research Use Only

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# 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 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® 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.[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® 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. 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® TBNEG-30
**Part Number:** **M115**
Kit Contains: 30 TBNEG bottles x 1.0mL