GENETIC ASSAYS
A Molecular Diagnostics Laboratory

MYCO Mycobacteria DNA by PCR - Qualitative

GA Test Code	**250**
Method	Real-Time Polymerase Chain Reaction (rPCR) – Qualitative
PCR/Probe Targets	**Mycobacteria DNA** (all known species) ***Mycobacterium avium*** species ***Mycobacterium intracellulare*** species ***Mycobacterium tuberculosis*** complex
Specimens	**Bronchial Washings**: 3.0 (min 1.0) mL, ambient (24 hrs) or refrigerated (7 days), in sterile plastic leak-proof container. Ship with cold pack. **Sputum**: 10.0 (min 5.0) mL, ambient (24 hrs) or refrigerated (7 days) in sterile plastic leak-proof container. For best results, collect 3 consecutive early morning samples. Ship with cold pack. **Positive AFB (Concentrate/Liquid Media)**: 1.0 (min 0.5) mL, ambient (24 hrs) or refrigerated (7 days), in sterile plastic leak-proof container, double-bagged with absorbent cloth. Acceptable media include AFB concentrate resuspended in buffer solution, BacT/ALERT, BACTEC, and Trek. **Positive AFB (Solid Media)**: submit swab or small portion of colony (e.g. LJ medium), ambient (24 hrs) or refrigerated (7 days). Ship with cold pack. **CSF**: 1.0 (min 0.3) mL, refrigerated (7 days) in sterile leak-proof container. **Bodily Fluid (e.g. pleural fluid)**: 3.0 (min 1.0) mL, ambient (24 hrs) or refrigerated (7 days), in sterile plastic leak-proof container. Ship with cold pack. **Fresh tissue**: 3 mm^3, refrigerated (7 days) or frozen. **Other Samples**: Please contact GA for questions about other specimens.
Causes for Rejection	Quantity not sufficient (QNS); time/temperature instructions not followed.
Reference Range	Not Detected
Turnaround Time	24-72 Hours
CPT Codes	87551, 87556, 87561 (x2)

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing.Real-Time PCR is used to amplify the 16S rRNA gene to detect all known species of mycobacteria, and the IS6110 gene, which is specific to the *M. tuberculosis* complex. The *Mycobacterium tuberculosis* complex consists of *M. tuberculosis, M. bovis, M. bovis BCG, M. africanum, M. microti,* and *M. canettii*. This assay detects as few as 10 cells/sample for species in the *M. tuberculosis* complex and 50 cells/sample for atypical mycobacteria. The sensitivity of this assay compared to culture is 95% for the *M. tuberculosis* complex and 85% for atypical mycobacteria.

Clinical Utility

According to the CDC, nucleic acid amplification testing should be performed on at least one respiratory specimen from each patient with symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not been established, and for whom the test result would alter case management of TB control activities. Compared with AFB smear microscopy, an added value of DNA testing lies in its ability to confirm rapidly the presence of *M. tuberculosis* in AFB smear-negative, culture-positive specimens.

CDC, Updated Guidelines for the Use of Nucleic Acid Amplification Test in the Diagnosis of Tuberculosis. MMWR 2009; 58(01); 7-10.

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