



MYCO

Mycobacteria DNA by PCR - Qualitative

GA Test Code	250
Method	Polymerase Chain Reaction (PCR) – Qualitative
PCR/Probe Targets	<i>Mycobacterium tuberculosis</i> complex <i>Mycobacterium avium</i> species <i>Mycobacterium intracellulare</i> species Mycobacteria Genus Note: for identification of Genus detected samples, order GA test code #1000 Reflex to Mycobacteria DNA Sequencing (Genotyping)
Specimens	Bronchial Washings and Body Fluids: 3.0 mL (1.0 mL), ambient (24 hrs) or refrigerated (7 days), in a sterile leak-proof container. Ship on cold pack. Sputum: 10.0 mL (5.0 mL), ambient (24 hrs) or refrigerated (7 days). For best results, collect at least 3 consecutive early morning samples. Ship on cold pack. BACTEC 12B: 1.0 mL (0.5 mL), a growth index of >50 is sufficient, or a small colony from a slant liquid culture (e.g. LJ medium). CSF: 1.0 mL (0.2 mL), refrigerated (7 days). AFB Smear: 1.0 mL (0.5 mL), decontaminated concentrate for culture, ambient (24 hrs) or refrigerated (7 days). Ship on cold pack. Biopsy: fresh tissue (preferred), 3 mm ³ , refrigerated (7 days) or frozen; for formalin-fixed, paraffin-embedded blocks, six 3-micron sections <i>preferred</i> , ambient; for needle biopsy , 2.0 mL (1.0 mL), refrigerated or frozen. Urine: 10.0 mL (5.0 mL), refrigerated (7 days). Other Samples: Please contact GA for questions about other specimens.
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed; swab specimens are not acceptable.
Reference Range	Not Detected
Turnaround Time	24-48 hours
CPT Codes	87551, 87556, 87561 (x 2)

Description

This assay uses PCR to amplify the IS6110 gene, which is specific to the *M. tuberculosis* complex, and the 16S rRNA gene. It detects as few as 10 cells/sample for species in the *M. tuberculosis* complex and 200 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. Genus and species specific probes are used to differentiate positive samples.

Clinical Utility

According to the Center for Disease Control (CDC), nucleic acid amplification testing should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet 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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