



MYCA

Mycobacteria DNA by PCR w/ AFB Culture

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| GA Test Code | 275 |
| Method | Real-Time Polymerase Chain Reaction (rPCR) – Qualitative Acid Fast Bacilli (AFB) Smear/Stain & Culture |
| PCR/Probe Targets | Mycobacteria DNA (all known species) <i>Mycobacterium avium</i> species <i>Mycobacterium intracellulare</i> species <i>Mycobacterium tuberculosis</i> complex |
| Specimens | Bronchial Washings: 3.0 (min 1.5) 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. CSF: 1.0 (min 0.5) 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; up to 6 weeks for AFB Culture results |
| CPT Codes | PCR: 87551, 87556, 87561 (x2); Culture: 87015, 87206, 87116 |

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. Patient samples are divided and then tested by Real-Time PCR and processed for AFB smear and culture at the same time. 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.

Real-Time PCR results should be interpreted in conjunction with the AFB smear results. Culture remains the gold standard for laboratory confirmation of TB and is needed for bacterial drug-susceptibility screening and genotyping.

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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