M. tuberculosis Complex versus Non-Tuberculous Mycobacteria by PCR on Smear Positive Specimens

Background Information

Mycobacterium tuberculosis infects one-third of the world's population and worldwide is the leading cause of death due to any infectious agent. The incidence of nontuberculous mycobacteria (NTM) infections is increasing, and NTM isolates now are more common in the United States than *M. tuberculosis*. Strict isolation is required under Centers for Disease Control and Prevention guidelines for all patients suspected of having tuberculosis; isolation is not required for patients infected with NTM. Treatment of tuberculosis and NTM also differs.

The ability to rapidly and accurately distinguish *M. tuberculosis* from NTM has significant clinical implications. This information should dictate appropriate infection control measures and guide the selection of appropriate antimicrobial therapy.

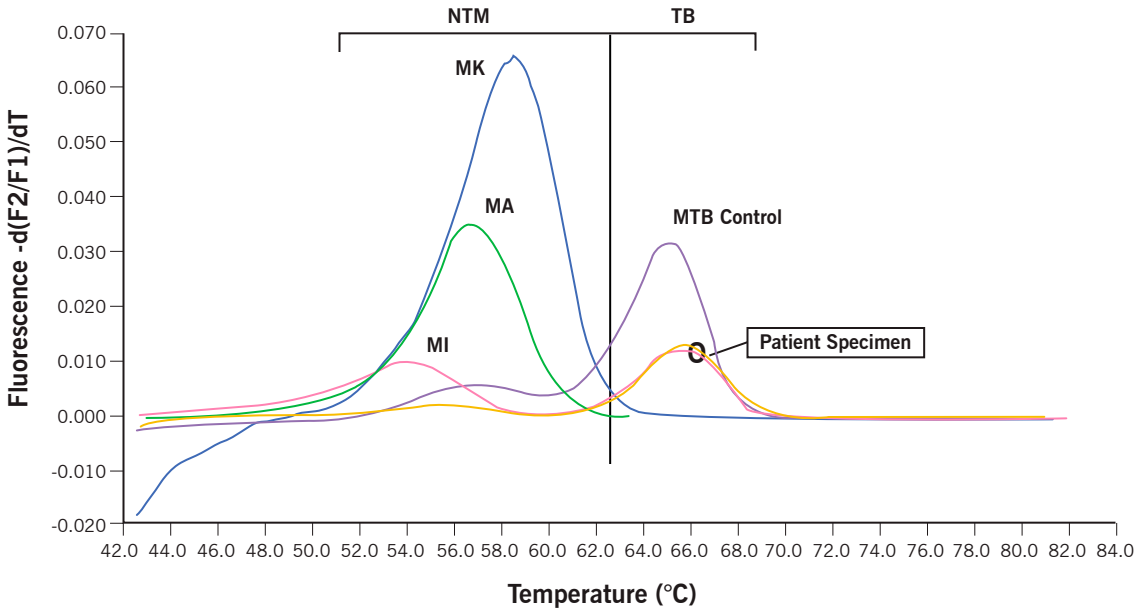
The LightCycler system (Roche Diagnostics, Indianapolis, Ind.) combines real-time PCR with fluorogenic hybridization probes using fluorescence resonance energy transfer probes. This assay achieves rapid PCR results and has high sensitivity and specificity for the majority of clinically relevant mycobacteria, including *M. tuberculosis*, when smear-positive specimens are tested. Melting curve analysis performed by the LightCycler allows for differentiation of *M. tuberculosis* from NTM.

Clinical Indications

Detection and differentiation of *M. tuberculosis* from NTM on smear-positive specimens. Culture for Mycobacterium spp should be performed on all specimens ordered for acid-fast bacilli because of the possibility of dual mycobacterial infections and to have the isolate available for susceptibility testing if appropriate.

Interpretation

Results are reported qualitatively as positive or negative for *M. tuberculosis*, and positive or negative for NTM.



Limitations of the Assay

This assay, as well as commercially available assays, is insensitive when smear-negative specimens are tested. This assay has suboptimal sensitivity for some of the rapidly growing *Mycobacterium* species and *M. xenopi*.

Methodology

The LightCycler FastStart DNA Master Hybridization Probe Kit (Roche) is used in conjunction with broad-range mycobacterial PCR primers and specially designed FRET hybridization probes. Rapid-cycle PCR and post-amplification melt curve analysis is performed in the LightCycler system.

Reference

1. Shrestha NK, Tuohy MJ, Hall GS, Reischl U, Gordon SM, Procop GW. Detection and Differentiation of *Mycobacterium tuberculosis* and nontuberculous mycobacterial isolates by real-time PCR. *J Clin Microbiol* 2003;41:5121-6.

Test Overview

Test Name	*M. tuberculosis*/NMT by real-time PCR
Reference Range	Negative for *Mycobacterium* spp
Specimen Requirements	Smear-positive respiratory specimens or tissue samples ordered for acid-fast bacilli
Ordering Mnemonic	TBPCR
Billing Code	87822
CPT Code	87551

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