



Technical Bulletin

Rapid PCR Testing for Mycobacterium tuberculosis

TO: Medical Staff and Clients

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SUBJECT: **Rapid testing for tuberculosis infection and rifampin resistance**

Diagnostic Laboratory Services, Inc. (DLS) provides rapid PCR *in vitro* diagnostic testing for the detection of *Mycobacterium tuberculosis* (MTB) complex DNA. Testing is performed on concentrated induced or expectorated sputum specimens. In specimens where *M. tuberculosis* complex DNA is detected, the assay also detects mutations in that DNA associated with rifampin-resistance.

This test must always be used in conjunction with mycobacterial culture (**order code 651**). Culture is necessary to recover MTB from patients that may be falsely negative due to PCR inhibition or infections below the PCR detection threshold. Isolates are necessary for further characterization, confirm rifampin resistance/susceptibility, and to perform additional drug susceptibility testing.

The test is intended for use with pulmonary specimens from patients for whom there is clinical suspicion of tuberculosis (TB) and who have received no antituberculosis therapy, or less than three days of therapy. Although 3 specimens are typically submitted, only one will be tested by PCR unless additional testing is approved by DLS (for example, if 2 of 3 specimens are acid fast bacilli (AFB) smear positive but the specimen tested by PCR was AFB smear negative, additional testing may be requested).

Although not FDA-approved for use in the evaluation of patients suspected of having extrapulmonary TB, DLS has validated its use on these types of specimens. Culture is required on these specimens as well.

A test result of “MTB NOT DETECTED” is highly predictive of an “AFB smear negative” status in patients with suspected active pulmonary tuberculosis and can be used as an aid in decisions regarding airborne isolation precautions, along with specific clinical circumstances and institutional guidelines. It should not be the sole basis for infection control practices.

Test order code: 6555
Acceptable Specimen: Sputum, extrapulmonary specimens (tissue, fluids, stool, etc.)
Optimal Specimen Volume: 2 mL
Ambient Stability: 3 days Refrigerated Stability: 10 days

Please refer any questions to Tori Enomoto, Manager - DLS Microbiology Laboratory at 808-441-5470, or DLS Client Services at 808-589-5101.