

## **Technical Bulletin**

## Rapid PCR Testing for Mycobacterium tuberculosis Available in Guam

**TO:** Medical Staff and Clients

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**DATE:** March 18, 2019

SUBJECT: Rapid testing for latent tuberculosis and rifampin resistance is now available in Guam

Diagnostic Laboratory Services, Inc. (DLS), in partnership with Guam Department of Health and Social Services (GDPHSS), is pleased to announce the availability of a rapid PCR *in vitro* diagnostic test for the detection of *Mycobacterium tuberculosis* (MTB) complex DNA in Guam. Testing is performed on unconcentrated induced or expectorated sputum specimens. In specimens where *M. tuberculosis* complex is detected, the assay also detects mutations associated with rifampin-resistance; however, **culture is required** to confirm either rifampin resistance or susceptibility (due to other mechanisms of rifampin resistance).

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. This test is intended to aid in the diagnosis of pulmonary tuberculosis, and must be used in conjunction with clinical and other laboratory findings. It is not for use in the evaluation of patients suspected of having extrapulmonary TB.

Testing for extrapulmonary disease may be performed at DLS-Hawaii for some specimens with clinical consultation / correlation. Please contact DLS Client Services if extrapulmonary testing is desired.

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 <u>not</u> be the sole basis for infection control practices.

This test must <u>always</u> be used in conjunction with mycobacterial culture (**order code 651**), which is performed at DLS-Hawaii. 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.

Test order code: 16555

Acceptable Specimen: Respiratory Specimen

Optimal Specimen Volume: 2 mL Ambient Stability: 3 days Refrigerated Stability: 10 days

Please refer any questions to Terrie Koyamatsu, Manager - DLS Microbiology Laboratory at 589-5196, or DLS Client Services at 589-5101.