COUNTY OF SAN LUIS OBISPO
PUBLIC HEALTH LABORATORY

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LABORATORY TEST FACT SHEET

TEST: MTB COMPLEX NAAT (Xpert) ORDER CODE: 3530

TEST DESCRIPTION

The *Mycobacterium tuberculosis* (MTB) complex nucleic acid amplification test (NAAT) is a qualitative, real-time polymerase chain reaction (PCR) method for the *in vitro* diagnostic detection of *Mycobacterium tuberculosis complex* DNA and rifampin resistance in acid-fast bacilli (AFB) smear-positive and smear-negative respiratory specimens. The Cepheid Xpert MTB/RIF assay is used to perform this test.

Specimens may be MTB/RIF negative and *M. tuberculosis complex* culture positive. This finding result from low numbers of *M. tuberculosis* or the presence of inhibitory substances, such as lectins, in the sample. Assay interference may occur in the presence of Lidocaine, mucin, ethambutol, guaifenesin, phenylephrine, or tea tree oil.

The MTB/RIF test is not indicated for use with specimens from patients being treated with antituberculosis agents to determine bacteriologic cure or to monitor response to such therapy.

Specimens that are grossly bloody should not be tested; blood may cause nonspecific positivity in the MTB/RIF Assay. The performance of the Xpert MTB/RIF Assay has not been evaluated with samples from pediatric patients.

A positive test does not necessarily indicate the presence of viable organisms.

Sensitivity and Specificity
For the MTB target, the sensitivity for AFB smear-positive specimens has been reported at 99.4% (479/482) and the sensitivity for AFB smear-negative specimens at 67.2% (135/201). The sensitivity of one Xpert MTB/RIF Assay result for the detection of RIF resistance has been reported at 94.7% (18/19). A negative test does not exclude the possibility of isolating an *M. tuberculosis complex organism* from the specimen. The efficacy of this test has not been shown for other clinical specimens (e.g., blood, CSF, tissue, urine, or stool). The specificity of the Xpert MTB/RIF Assay for the detection of MTB and RIF resistance has been reported at 98.7% (1355/1373) and 99.0% (404/408), respectively.

SPECIMENS ACCEPTED FOR TESTING

- Sputum and/or concentrated digested sputum (minimum volume of 5 ml)
- Bronchial washings/aspirate (minimum volume of 1 ml)
- Store specimens at 2–8 °C, with a maximum hold time of 72 hours.
- Note: The San Luis Obispo County Laboratory has also validated the assay for solid and liquid media culture isolates.

CPT code: 87556