



GeneXpert(R) MTB/RIF Provider Information and Guidelines for Interpretation

What is it?

Xpert(R) MTB/RIF or TB GeneXpert is a rapid test that can simultaneously identify *Mycobacterium tuberculosis* (MTB) and resistance to rifampin from sputum. It is a nucleic acid amplification method that has been designed as an integrated DNA extraction and real time PCR system that is safe and simple to use. It can deliver test results in less than two hours from concentrated sputum specimens.

How does it work?

TB GeneXpert has been designed as a point-of-care test, so processing is simple. A reagent is added to a concentrated sputum pellet to liquefy the specimen and kill any mycobacteria within. The cartridge is loaded into the GeneXpert Analyzer, which subsequently detects the presence of TB DNA and any mutations that confer rifampin resistance. Internal controls are present within each cartridge to assess the presence of inhibitors that may cause false negative results. The test is not FDA-approved, but its performance characteristics have been determined at the San Francisco Department of Public Health Laboratory (SFPDH Laboratory).

Performance

A recent study by Helb et al demonstrated 100% (29/29) sensitivity in smear-positive, culture-positive specimens and 71.7% (38/53) sensitivity in smear-negative, culture-positive specimens. The specificity of the test was 100% for MTB and rifampin-resistance detection, and the predicted limit of detection was determined at 131 colony forming units per millileter (J.Clin Microbiol.2009; 48(1): 229-37). An assessment of the sensitivity and specificity of the test performed by the SFPDH Laboratory has resulted in very similar findings. Local validation of rifampin resistance results will require further study because of the small number of specimens available for testing.

Selected Use

Use of the test is limited to ambulatory TB Clinic patients who are strongly or moderately suspected of having pulmonary TB (ATS Classification TB5 High or TB5 Moderate). The test is NOT available to hospitalized patients at this time. Please do not call the laboratory to request this test.

The first collected sputum specimen will be sent for testing at the SFPDH Laboratory.

Note: The test will be run 3 days per week and results will be faxed to our surveillance unit.

Test Interpretation?

Positive TB GeneXpert result: Use as confirmation for tuberculosis and start TB treatment

Negative TB GeneXpert result and NOT on TB treatment: No action should be taken.

Negative TB GeneXpert result and on TB treatment for active disease: One of several selected TB Clinic physicians will perform a case review to determine if treatment can be stopped.

Limitations

No diagnostic test can replace clinical judgment.

Like all diagnostic tests, the TB GeneXpert result must be used carefully with other clinical information, especially when deciding to stop TB treatment. Sensitivity is significantly affected by the number of organisms in the specimen, and false negative results are much more likely in smear-negative sputum specimens, where sensitivity of the test has been found in separate studies to be approximately 72%. A minimum volume of 0.5 ml of concentrated specimen is required for this test.