

FACT SHEET

M tuberculosis Amplification (GeneXpert MTB-RIF)

Test 3530

Test Description:

Mycobacterium Tuberculosis (MTB) Amplification test (Cepheid GeneXpert MTB-RIF) 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

Samples may be MTB-RIF negative and M. tuberculosis complex culture positive. This condition may be caused by inhibitory substances such as lectins, or the low numbers of the M. tuberculosis in the sample.

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

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

Assay interference may be observed in the presence of Lidocaine (>20% v/v), mucin (>1.5% w/v), Ethambutol (>5 µg/mL), Guaifenesin (>2.5 mg/mL), Phenylephrine (>25% v/v), or tea tree oil (>0.008% v/v).

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

Sensitivity has been reported as 90.9-98.4 % 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 demonstrated other clinical specimens (e.g., blood, CSF, tissue, urine, or stool).

Specificity has been reported to vary from 89 to 100% in various studies.

Specimen:

- Sputum and/or Concentrated Digested Sputum minimum 5 ml
- Bronchial Washings/Aspirate minimum 1 ml
- Store specimen(s) at 2-8 C
- Maximum Holding time 72 hours.

CPT: 87556



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LITERATURE SUMMARY

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The table summarizes the sensitivity and specificity of the Amplified Mycobacterium tuberculosis Direct Test (MTD, Hologic-Gen-Probe) and the Gene Xpert MTB-RIF assay (Cepheid, Inc) for detection of *M. tuberculosis* nucleic acid in primarily respiratory specimens.

NAAT	Specimens n=	Sensitivity	Specificity	Ref
MTD	1,151 resp.	91.7% overall 98.7 % smear pos 62.2 % smear neg	98.7 % overall 97.8% smear pos 98.9% smear neg	1
MTD	162 resp	97.3% overall	87.1.% overall	2
Gene Xpert	+non-resp	90.9% overall	89.0%	2
Gene Xpert	107 resp	100% smear pos 71.7% smear neg	100%	3
Gene Xpert	85 resp	75.3% smear neg	100%	4
MTD	31 resp 4 resp	93.5% smear pos 75% smear neg		5
Gene Xpert	217 resp	98% smear pos 72% smear neg		6
Gene Xpert	27 35	100% smear-pos 68.6% smear neg		7

References:

1. R L. Guerra, MD; N M. Hooper, JF. Baker, et al Use of the Amplified *Mycobacterium tuberculosis* Direct Test in a PublicHealth Laboratory-Test Performance and Impact on Clinical Care
Chest 132: 946-951. 2007.
- 2 J Teo, R Jureen, D Chiang, D Chan and R Lin. Comparison of Two Nucleic Acid Amplification Assays, the Xpert MTB/RIF Assay and the Amplified Mycobacterium tuberculosis Direct Assay in for Detection of Mycobacterium tuberculosis in Respiratory and Non-respiratory Specimens.
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3. D Helb, M Jones, E Story, et al. Rapid Detection of *Mycobacterium tuberculosis* and Rifampin Resistance by Use of On-Demand, Near-Patient Technology. J. Clin. Microbiol., 48:229. 2010.
4. R Moure, L Munoz, M Torres et al. Rapid Detection of *Mycobacterium tuberculosis* Complex and Rifampin Resistance in Smear-Negative Clinical Samples by Use of an Integrated Real-Time PCR Method. J. Clin. Microbiol., 49:1137. 2011.

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5. L Han, PEIvin, and JBernardo. Nonclinical Selection Criteria for Maximizing Yield of Nucleic Acid Amplification Tests in Tuberculosis Diagnosis. *J. Clin. Microbiol.*, 50:2592. 2012.
6. E Marloew, S Novak-Weekley, J Cumpio, et al. Evaluation of the Cepheid Xpert MTB/RIF Assay for Direct Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens. *J. Clin. Microbiol.*, 49:1611. 2011.
7. A Zeka, S Tasbakab, and C Cavusoglu. Evaluation of the GeneXpert MTB/RIF Assay for Rapid Diagnosis of Tuberculosis and Detection of Rifampin Resistance in Pulmonary and Extrapulmonary Specimens *J. Clin. Microbiol.*, 49:4138. 2011.