

CITY AND COUNTY OF SAN FRANCISCO PUBLIC HEALTH LABORATORY

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Test Order

Identification of Mycobacterium tuberculosis Complex by Real-Time PCR

Synonym(s)	Mycobacterium tuberculosis complex Detection and Rifampin Resistance Detection by PCR
Methodology	Real-time PCR (Cepheid GeneXpert)
Acceptable Specimen Type(s) for Testing	Sputum (expectorated or induced) sediment
Transport / Collection Medium	Sterile collection vial
Storage and Preservation of Specimen	Keep sediments refrigerated 2-8°C for a maximum of 10 days. Storage beyond 10 days must be at -35°C or below.
Minimum Volume Required	0.5 mL sputum sediment
Additional Collection Instructions	Only concentrated sputum sediments accepted
Additional Required Information	Collection date required
Send Out?	No
Turnaround Time	24 hours
Testing Restrictions	
Requisition Form(s)	http://sfcdcp.org/document.html?id=1035
Limitations / Notes / Disclaimers	Detection of <i>Mycobacterium tuberculosis</i> complex (<i>M.tb.</i> complex) by this assay is dependent upon the number of organisms present in the sample. Hence, reliable results require proper specimen collection, handling, and storage. Careful compliance to this protocol is essential for avoiding erroneous results. A positive test result does not necessarily denote the presence of viable organisms, but is presumptive for the presence of <i>M.tb.</i> complex. Mutations or polymorphisms in either the primer or probe binding sites of the target organisms may negatively affect the detection of novel or unknown strains of <i>M.tb.</i> complex. Moreover, some specimens with very few viable organisms will be negative by this assay, but may be positive by culture.

Updated 2/10/2017