

Louisiana Office of Public Health Laboratories

Test Name	<i>Mycobacterium tuberculosis</i> (MTB) Nucleic Acid Amplification Test (NAAT)
PHL Location	Central Laboratory
CPT Code	87556
Synonyms	N/A
Brief Description of Test	Nucleic Acid Amplification Test performed on concentrated sputum specimens to detect the presence of <i>Mycobacterium tuberculosis</i> Complex (MTB) and Rifampin resistance
Possible Results	MTB Not Detected MTB Detected; Rifampin Resistance Detected MTB Detected; Rifampin Resistance Not Detected MTB Detected; Rifampin Resistance Indeterminate
Reference Range	N/A
Specimen Type	Sputum (expectorated or induced)
Specimen Container(s):	See storage and transport instructions. Specimens must be labeled with two patient identifiers which match the identifiers on the lab submission form.
Minimum volume accepted:	Minimum Acceptable Volume is 1 mL
Collection Instructions	For sputum, 5-10 ml of an early morning specimen, should be collected prior to eating. Minimal acceptable collection volume is 1mL. For accurate diagnosis three specimens should be collected during three consecutive 8 to 24 hour intervals (24 hour intervals are recommended when possible).
Storage and Transport Instructions	Sputum specimens should be collected in a laboratory-approved, sterile, leak-proof, non-breakable 50 ml conical tube or equivalent container. Specimens should be labeled with the date collected, patient's first and last name, and a unique identifying number (e.g. hospital accession number, patient medical record number, etc.). The date of birth should not be used for the unique identifying number. Identifiers MUST match the information on Lab Form 97. Sealed 50 mL specimen conical tubes and containers should be placed in an appropriate biohazard specimen bag containing absorbent material. The specimen bag should be

	<p>sealed and the lab form inserted into the outside pocket of the bag.</p> <p>Sealed specimen bags must be transported to the laboratory at 2°- 8°C in a refrigerated, rigid, outer container and should be processed by the laboratory ≤120 hours post-collection.</p> <p>A Lab form 97 must be completed with all required information. Mandatory submission information includes: Patient first and last name, date of birth, gender, second unique identifier, date and time of collection, test requested, specimen source, and submitter information.</p>
<p>Causes for Rejection</p>	<ul style="list-style-type: none"> • Leaking or broken container • Lab form 97 is missing required information • No Lab form 97 received with specimen • Mislabeled or unlabeled specimen • Specimen received outside of the limits of acceptable transport temperature • Specimen unable to be processed by the laboratory within 120 hours post collection • Specimens received with a volume <1 mL
<p>Limitations of the Procedure</p>	<ul style="list-style-type: none"> • MTB NAAT is not indicated for use with sputum samples from patients being treated with antituberculosis drugs either to determine bacteriologic cure or to monitor response to therapy. • A negative test does not exclude the possibility of isolating MTB-complex from the sputum sample. The MTB NAAT must be used in conjunction with mycobacterial culture to address the risk of false negative results and to recover the organism for further characterization and susceptibility testing. • A positive test does not necessarily indicate the presence of viable organisms. • The MTB NAAT does not differentiate between the species of the MTB-complex.
<p>Interfering Substances</p>	<p>N/A</p>
<p>References</p>	<ul style="list-style-type: none"> • Xpert® MTB/RIF Assay. Cepheid, May 2016.
<p>Additional Information</p>	<p>Use Lab Form 97 and supply the following information:</p> <ul style="list-style-type: none"> • Patient’s first and last name • Second Unique Identifier • Gender • Date of birth • Date and time specimen was collected • Source of specimen • Test requested

	<ul style="list-style-type: none">• Submitter's name, address, telephone number, fax number and contact person.
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