

## ***Mycobacterium tuberculosis* complex nucleic acid amplification test (MTBC NAAT)**

<b>Test Description</b>	A nucleic acid amplification test for the direct detection of <i>Mycobacterium tuberculosis</i> complex (MTBC) DNA in pulmonary specimens. The test also detects mutations of the <i>rpoB</i> gene, an indicator of rifampin resistance.
<b>Test Use</b>	This test is intended as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings.
<b>Test Department</b>	Mycobacteriology Laboratory Phone: (860) 920-6649 FAX: (860) 920-6721
<b>Methodology</b>	Xpert® MTB/RIF : Qualitative, nested real-time polymerase chain reaction (PCR)
<b>Availability</b>	Daily, Monday-Friday
<b>Specimen Requirements</b>	A minimum of 3 mL (5-10 mL preferred) raw, unprocessed sputum, bronchial lavage, or bronchial washings from patients who have received no antituberculosis therapy, or less than three days of therapy at the time of specimen collection. Specimens must be received by the laboratory within 10 days of collection.
<b>Collection Kit/Container</b>	To obtain collection kit, refer to Collection Kit Ordering Information
<b>Collection Instructions</b>	Collect specimen into sterile container. Collection instructions may be obtained by calling the Mycobacteriology laboratory.
<b>Specimen Handling &amp; Transport</b>	Store specimen at 2°-8°C. Transport to the laboratory as soon as possible with an ice pack coolant (preferred) or at ambient temperature. Avoid temperature extremes. Specimens must be received by the laboratory within 10 days of collection.
<b>Unacceptable Conditions</b>	Unlabeled specimen Specimens that have leaked or containers that have broken in transit Extra-pulmonary specimens Processed pulmonary specimens or sediments
<b>Requisition Form</b>	Clinical test requisition (select <b>AFB Clinical Specimen</b> ) Nucleic Acid Amplification Test Requisition may be found at the Dr. Katherine A. Kelley State Public Health Laboratory webpage located at, <a href="http://www.ct.gov/dph/cwp/view.asp?a=3122&amp;q=396860">www.ct.gov/dph/cwp/view.asp?a=3122&amp;q=396860</a>
<b>Required Information</b>	Name and address of submitter (and/or Horizon profile #). Patient name or identifier, town of residence (city, state, zip) date of birth. Specimen source/type, date collected, test requested. Please ensure patient name or identifier on requisition matches that on the specimen.
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• A positive test does not necessarily indicate the presence of viable organisms</li> <li>• A negative test does not exclude the possibility of isolating MTBC from the specimen.</li> <li>• The test should NOT be ordered when clinical suspicion is low, to determine bacteriologic cure, or to monitor response to anti-tuberculosis drug therapy.</li> </ul>
<b>Additional Comments</b>	<ul style="list-style-type: none"> <li>• This test is automatically done on the first patient specimen submitted for AFB smear and culture that is found to be acid fast smear positive. Testing of AFB smear negative specimens is only performed upon request (See <b>Requisition Form</b>).</li> <li>• Acid fast microscopy and Mycobacterial culture is also performed on all specimens tested by MTBC NAAT to address the risk of false negative results and to recover the organism for further characterization and susceptibility testing.</li> </ul>

Revision: 03/05/2018