

Test Menu

TOPIC	DESCRIPTION
Test Name	Real-time PCR (rtPCR) Nucleic Acid Amplification Test (NAAT) for TB IS6110 sequence.
Other Name (s)	Nucleic Acid Amplification Test for <i>Mycobacterium tuberculosis</i> complex (MTBC)
Analyte(s)	Detects the IS6110 sequence
Test Code	3140
Lab location	Jacksonville location
Department	Mycobacteriology (TB)
Pre-Approval Required	Pre-approval required for non-respiratory specimens. Pre-approval required for specimens arriving > 7 days from date of collection.
Required Forms	BPHL requisition Form, DH1857 (Not needed if ordered via WebLIMS)
Specimen Sources	Respiratory specimens (5 ml minimum) or CSF. Processed specimens are acceptable.
Supplemental Information- Special Specimen Preparation	> 5 ml of unprocessed specimen or 0.5 - 1 ml of processed specimen in 50 ml sterile conical tube, shipped in double container. Gastric lavage specimens must be neutralized with 100 mg of sodium carbonate if the time between collection and processing exceeds 4 hours. This test cannot be performed on blood specimens. Specimens should be stored refrigerated until time of shipment. Urine should be shipped refrigerated. Specimens may be shipped within the 2-28°C temperature range or cold, using a cold pack. Specimens for Real-time PCR testing that arrive > 7 days from collection will require pre-approval.
Minimum Volume	> 5 ml of unprocessed specimen or 0.5 - 1 ml of processed specimen
Storage Conditions	Store refrigerated until time of shipment. May be shipped cold or ambient, but urine specimens must be shipped and arrive refrigerated (2 – 8 C).
Collection Media	> 5 ml of unprocessed specimen or 0.5 - 1 ml of processed specimen in 50 ml sterile conical tube
Specimen Labeling	Must have two unique patient identifiers, preferably name and date of birth. Submissions not meeting these criteria will be rejected.
Packaging and Shipping Instructions and Handling	Shipment temperature: ship within the 2-28°C temperature range, but urine specimens must be shipped and arrive refrigerated (2- 8°C)., Separation of specimens to prevent cross-contamination.
Test Methodology	Real-time PCR
Turnaround Time	48 hours
Result Indicator	Positive: Positive for MTBC DNA. Neg: Negative for MTBC DNA. Indeterminate: Inconclusive for MTBC DNA.
Unsatisfactory Specimen	Any non-respiratory specimens require prior approval from the TB Physician Network. Formalin fixed or paraffin-embedded tissues, no patient identification on specimen tube, no specimen observed in specimen tube, specimen damaged or leaked entirely in transit. Note: this test cannot be performed on blood specimens.
Interferences and Limitations	Formalin fixation, paraffin embedded tissue, blood specimens cannot be tested.
Additional Information & Notes	Positive specimens are automatically tested by GeneXpert, or HAIN test, and shipped to CDC MDDR if they are rifampin resistant. All specimens submitted with just 3140 (NAAT) will also have smear and culture performed.
Reference Range	Negative for MTBC by real-time PCR.
Reference Lab	Paraffin embedded tissue can be sent to CDC Infectious Disease Pathology Branch (IDPB) for NAAT testing. Requires prior approval from the TB Physician Network.
Reflex testing	GeneXpert if rtPCR Positive