

**Test Menu**

<b>TOPIC</b>	<b>DESCRIPTION</b>
Test Name	Real-time PCR (rtPCR) Nucleic Acid Amplification Test (NAAT) for TB Insertion Sequence 6110 (IS6110).
Other Name (s)	Nucleic Acid Amplification Test for <i>Mycobacterium tuberculosis</i> complex (MTBC)
Analyte(s)	Detects IS6110
Test Code	3140
Lab location	Jacksonville location
Department	Mycobacteriology (TB)
Pre-Approval Required	Non-respiratory specimens, and specimens > 7 days from date of collection require prior approval from the Florida TB Physician Network.
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	Gastric lavage specimens must be neutralized with 100 mg of sodium carbonate if the time between collection and processing exceeds 4 hours.
Minimum Volume	> 5 ml of unprocessed specimen or 0.5 - 1 ml of processed specimen
Storage Conditions	Store refrigerated until time of shipment.
Collection Media	N/A
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	Specimens can be shipped within the 2-28°C temperature range, except for urine specimens, which must be shipped refrigerated (2 - 8°C). Processed urine sediments may be shipped within the 2-28°C temperature range and must be clearly marked on the requisition as "Processed". 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	Formalin fixed or paraffin-embedded tissues. No patient identification on specimen. No specimen observed in specimen tube, specimen damaged or leaked entirely in transit. Blood specimens. Gastric aspirates that have not been neutralized. Urine specimens arriving outside of acceptable temperature.
Interferences and Limitations	Specimens contaminated by blood. A positive result indicates the DNA of <i>Mycobacterium tuberculosis</i> complex is present does not necessarily indicate viable organism.
Additional Information & Notes	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	Positive specimens – GeneXpert MTB/RIF

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