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Date: January 3, 2022 at 12:09:52 PM EST

Subject: DTBE Laboratory Branch: Changes in pre-analytic requirements for laboratory testing

Dear Colleagues,

The purpose of this communication is to notify submitters to the Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination Laboratory Branch (LB) of recent, required changes in the pre-analytic requirements for testing. These changes apply to **all submissions** including those for the Molecular Detection of Drug Resistance (MDDR) testing service for *Mycobacterium tuberculosis* complex (MTBC).

Beginning January 3, 2022, public health laboratories will need to contact LB at TBLab@cdc.gov for **pre-approval** prior to submitting samples for testing. Previously, pre-approval was only required for MDDR requests; however, the pre-approval requirement will now also apply to requests for drug susceptibility testing (including agar proportion and MGIT for pyrazinamide) and *Mycobacterium tuberculosis* complex identification through at least February 7, 2022.

Revised specimen requirements are described below. Please note that we are no longer accepting DNA extracts from submitters external to CDC for MDDR testing.

- **Acceptable Sample Types:**
 - MTBC nucleic acid amplification test-positive (NAAT+) sediment
 - Pure MTBC isolate on solid medium or in broth medium
 - Mixed cultures known to contain MTBC
- **Acceptable Collection, Storage and Preservation Prior to Shipping:**
 - NAAT+ sediments: Stored at 2 to 8°C up to 30 days post collection; - 20°C or lower up to 60 days post collection
 - MTBC isolates: Stored at 2 to 8°C up to 120 days post collection (solid & liquid media); 15 to 25°C up to 120 days post collection (solid & liquid media); - 20°C or lower up to 120 days post collection (liquid media); -65°C or lower up to 5 years post collection (liquid media)
- **Minimum Volume Required:**
 - NAAT+ sediment: Submit at least 0.5 mL, 1 mL preferred
 - MTBC isolates in liquid medium: Submit at least 0.5 mL, 1 mL preferred
- **Acceptable Transport Medium:**
 - Solid media (i.e., Middlebrook 7H10 or 7H11 plates/slants, Lowenstein-Jensen (LJ) slants)
 - Liquid media (i.e., Middlebrook 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC growth from solid medium, suspended in saline or sterile water

For pre-approval of MDDR requests, submitters should complete all portions of the newly revised MDDR Request Form (attached) and submit this form via email to TBLab@cdc.gov, fax at 404-639-5491, or through the CDC Specimen Test Order and Report ([CSTOR](#)) web portal. Submissions not meeting these requirements are subject to rejection by CDC.

For pre-approval of other test requests, submitters should send an email to TBLab@cdc.gov indicating the test being requested and the date of collection of the sample. Submissions not meeting these requirements are subject to rejection by CDC.

Once approved, LB will send an email with further submission instructions. Please attach the approved MDDR request form or email communication to the CDC requisition ([Specimen Submission Form | Submitting Specimens to CDC | Infectious Diseases Laboratories | CDC](#)) when shipping. Specimen collection date is required on the 50.34 form. Please note, submitters must retain the original isolate/culture/inoculum in the submitting laboratory for the duration of testing at CDC. Only one sample per patient should be submitted; however, testing of duplicate samples will be considered on a case-by-case basis.

Shipping Instructions which Include Specimen Handling Requirements:

- Only ship at room temperature; sample must be received within 5 days of shipment.
- Submit sediment in a screwcap cryovial that has been sealed with parafilm; do not send in a 15- or 50-mL conical tube.
- Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. MTBC isolates must be shipped as infectious substances (Div. 6.2, Class Category A).
- CDC does not accept routine specimens on weekends or holidays. Please make sure packages arrive Monday–Friday.

Sediments and isolates should be shipped **standard overnight** to CDC using the following address.

TB Lab / Atanaska Marinova-Petkova
Centers for Disease Control and Prevention
RDSB/STATT Unit 29
1600 Clifton Road, NE
Atlanta, GA 30329
404-718-5254 or 404-639-2455

A dedicated FedEx account managed by the Association of Public Health Laboratories (APHL) can be used to support shipping for MDDR testing. Additional information regarding this shipping account can be obtained from APHL by contacting Anne Gaynor (anne.gaynor@aphl.org) or Taylor Bethea (taylor.bethea@aphl.org).

We appreciate your adherence to these revised submission criteria. If you have any questions regarding these requirements, please contact us at TBLab@cdc.gov.

Kind regards,

Angela

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