Molecular TB Proficiency Test Program (mTB-PT)
Dried Tube Specimen (DTS) Sample Testing Instructions

Dear Participant:

Thank you for participating in the US CDC, Global Health Center (GHC), Division of Global HIV and TB, International Laboratory Branch (ILB) Molecular TB Proficiency Test (mTB-PT) Program. Proficiency testing (PT) is an essential component of a quality assurance program. Participation in this program is voluntary and offered at no cost to participants. Participation and all submitted results will remain confidential; only your testing site, Proficiency Testing Country Coordinator(s) (PTCC), PT provider, and web management team will have access to individual testing site results, and results with site identifiers will not be shared externally without written consent.

CDC uses an online PT data management tool, called 'ePT,' for collection of PT results. Results for this panel **must** be submitted in ePT by the submission deadline to receive a scored report. Instructions on how to enter results into the ePT system can be found at **http://mTBePT.com/**

This panel must be tested with either the Xpert MTB/RIF or Xpert MTB/RIF Ultra assay, collectively referred to as Xpert TB in mTB-PT panel documents.

Email your site's Proficiency Testing Country Coordinator (PTCC) or the US CDC/ ILB mTB-PT team XTPT@cdc.gov with any questions or concerns.

THANK YOU FOR YOUR PARTICIPATION

INSTRUCTIONS

Storage: If testing cannot take place immediately, store molecular TB proficiency test packet **under stable temperature conditions (2-45°C)** until testing.

1. **Inspect**

Please use the following list to determine if all proficiency test packet components are present.
- 1 plastic bag containing five labeled (1-5) Dried Tube Specimen (DTS) sample tubes
- 5 individually-wrapped transfer pipettes
- 1 result form

Inspect each of the five sample tubes to ensure dried blue material is present at the bottom of each tube, labels are intact and clearly legible, and tubes are undamaged. Please note the absence of blue material from any of the sample tubes in the comments section of the result form and in the ePT submission window but test the sample as instructed. If you received any duplicate or damaged samples or samples tube labels are illegible or no longer intact, report the issue to your PTCC immediately and request a replacement panel.

2. **Test**

 Caution: mTB-PT DTS samples contain nonviable strains of mycobacteria yet should be treated as infectious material. The DTS samples should only be opened in the dedicated testing space where the Xpert® MTB/RIF or Xpert® MTB/RIF Ultra (Xpert TB) assay is performed, using the same precautions and safety measures employed when testing clinical samples.

Testing Instructions:
- Treat proficiency test samples as clinical patient samples.
- Only rehydrate the number of DTS samples that can be tested immediately, store remaining DTS samples until modules are available for testing.
- Rehydrate DTS samples
  - Use the individually wrapped transfer pipettes included in the proficiency test packet to add 2.5 ml of sample reagent (SR) from the Xpert MTB/RIF or Ultra assay kit to the DTS.
  - Tighten the caps on the sample tubes.
- Incubate, mix and test as if testing patient samples.

3. **Report**
- Complete the Molecular TB Proficiency Test Result Form included in the test packet for your records.
- If a test results in an error, document the error code in the Error Code column.
- If a run fails, or you are unable to test a sample, please note the reason in the Comments section on the result form.
- **Enter the information from the completed result form into ePT, the mTB-PT online data management tool, using the instructions found at http://mTBePT.com/ and the ePT username and password on your paper result form. If you are unable to access the internet, submit the completed result form to your PTCC for assistance with ePT submission.**
- Following the submission deadline and after report finalization, a summary and individual testing site performance report will be available to you and your PTCC via ePT using the same login credentials.
- Results submitted by your testing site will be aggregated and added to the summary report but will remain anonymous.