**Subject:** Recent development on availability of PZA test kits

**Date:** Monday, December 9, 2024 at 12:31:52 PM Eastern Standard Time

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**To:** CDCL-TBLABORATORYCONTACTS@LISTSERV.CDC.GOV, CDC NCHHSTP DTE TB Control Officers, CDC NCHHSTP DTE TB Nurse Consultants, CDC NCHHSTP DTE TB Project Directors, CDC DDID NCHHSTP DTE TB Surveillance Coordinators, CDC NCHHSTP DTE TB COE, CDC NCHHSTP DTE Medical Consultants

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Dear Colleagues,

In late September, Becton, Dickinson and Company (BD) began releasing new lots of the BD BACTEC™ MGIT™ 960 PZA kits for susceptibility testing of *Mycobacterium tuberculosis* complex (MTBC) to pyrazinamide (PZA) after supply interruptions due to a Medical Device Correction that was implemented because of reported intermittent false resistance. BD issued another letter in November to inform customers that because of a recent raw materials error, batches of test kits that were in progress had to be discarded. Given this development, supply interruption is anticipated with BD BACTEC™ MGIT™ 960 PZA kits not available for shipment until early 2025.

Assistance with *pncA* sequencing of MTBC as described in the August 7, 2024, Dear Colleague Letter from CDC and the Association of Public Health Laboratories (APHL) is continuing. National data from 2018–2022 comparing whole genome sequencing (WGS) data for *pncA* to PZA phenotypic susceptibility test data show that *pncA* mutations have a 96% sensitivity and 94% specificity for predicting PZA phenotypic resistance in MDR TB patients. Please see the updated table below for where samples may be sent for testing, if needed.

Please note that CDC's MDDR service remains available to all jurisdictions for testing when drug resistance is known or suspected.

| Laboratory | States | POC |
|---|---|---|
| CA MDL | California, TB DST Reference Center Submitters | cdphtbdst@cdph.ca.gov |
| DTBE/LB | Alabama, Connecticut, Georgia, Illinois, Indiana, New Jersey, North Carolina, North Dakota, Ohio, Oregon, and Wisconsin | tblab@cdc.gov |
| FL BPHL | Florida | Patrick.valois@flhealth.gov |

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| TX DSHS | Arizona, Arkansas, Louisiana, Missouri, Tennessee, Texas, Virginia, and West Virginia | Jan.owen@dshs.texas.gov |
| Wadsworth | Delaware, Hawaii, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New York, Pennsylvania, Washington, and Washington DC | vincent.escuyer@health.ny.gov |

When triaging these requests, submitters should communicate with the testing laboratories to ensure that the number of specimens submitted is acceptable in terms of the testing laboratories' available capacity. If further prioritization of samples is required, submitting laboratories should work with their clinicians and TB programs to determine the best approach.

Please let us know if you have any questions. We will continue to provide updates as new information becomes available.

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