

Subject: Notification of expanded capacity for *pncA* sequencing for evaluating PZA susceptibility

Date: Wednesday, August 7, 2024 at 9:15:59 AM Eastern Daylight Time

From: Starks, Angela M. (CDC/NCHHSTP/DTE)

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

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Dear Colleagues,

As indicated in the July 25, 2024 letter from CDC's Division of TB Elimination (DTBE), phenotypic pyrazinamide (PZA) susceptibility testing may not be available in many laboratories because of a manufacturer issue. The list of affected lots was expanded in an August 1st communication from Becton, Dickinson and Company (BD). It is currently unknown when new BD BACTEC™ MGIT™ 960 PZA test kits might be available.

In response, CDC/DTBE is working collaboratively with the Association of Public Health Laboratories (APHL) and public health laboratory partners to provide additional capacity for *pncA* sequencing. Sequencing of *pncA* is an acceptable approach for determining PZA susceptibility as PZA resistance is primarily associated with *pncA* mutations.

The California Microbial Diseases Laboratory (CA MDL), Wadsworth Center in New York State (Wadsworth), the Texas Department of State Health Services in Austin (TX DSHS), the Florida Department of Health Bureau of Public Health Laboratories (FL BPHL) as well as CDC's DTBE Laboratory Branch (DTBE/LB) will be assisting with *pncA* sequencing of *Mycobacterium tuberculosis* complex isolates until new PZA test kits are available.

Please see the following table that outlines our initial plan for requesting *pncA* sequencing. **Please note that current submitters to the [National PHL DST Reference Center](#) at CA MDL will continue to receive services through the reference center and are not included in the table below.** Additionally, [CDC's MDDR service](#) remains available to all jurisdictions for testing when drug resistance is suspected or known.

Laboratory	States	POC
CA MDL	California, Hawaii, Minnesota, Nevada, and Washington	cdphtbdst@cdph.ca.gov
DTBE/LB	Alabama, Connecticut, Georgia, Illinois, Indiana, New Jersey, North Dakota, Ohio Oregon, and Wisconsin	tblab@cdc.gov
FL BPHL	Florida and North Carolina	Patrick.valois@flhealth.gov
TX DSHS	Arizona, Arkansas, Louisiana, Missouri, Tennessee, Texas, Virginia, and West Virginia	Jan.owen@dshs.texas.gov
Wadsworth	Delaware, Maryland, Massachusetts, Michigan, Pennsylvania, New York, and Washington DC	vincent.escuyer@health.ny.gov

The assignments above are for interim assistance and are meant to aid in balancing anticipated test volumes with the sequencing capacity available in each laboratory. As we learn more about the potential impacts and the need for testing, the assignments may need to be adjusted.

Please reach out to the contact as indicated in the table above. When reaching out to CA MDL, FL BPHL, TX DSHS, and Wadsworth to discuss testing needs, submission requirements, and other steps (e.g., onboarding for electronic reporting) that may be needed, please also copy Sarah Buss at APHL (sarah.buss@aphl.org). APHL will be working to schedule onboarding calls for each group of laboratories.

The demand may exceed the capacity for *pncA* sequencing. If you need this service because phenotypic PZA susceptibility testing is unavailable, you may need to prioritize which isolates will be referred for *pncA* sequencing.

- These might include isolates that are rifampin-resistant or multidrug-resistant (MDR) or isolates from patients whose treatment response is of concern.
 - Note: Isolates evaluated by CDC’s Molecular Detection of Drug Resistance (MDDR), or similar services, do not need to be resent for just *pncA* sequencing as this genetic locus is already included in the full panel for molecular testing.
- For situations when PZA might be essential for building a multidrug treatment regimen, but PZA susceptibility cannot be ascertained because of either the lack of testing or the presence of a *pncA* mutation where correlation with PZA resistance is unknown, consultation with the [Tuberculosis Centers of Excellence for Training, Education, and Medical Consultation](#) in conjunction with your [TB program](#) is strongly recommended.

Please let us know if you have any questions. We will provide updates as they become available.

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