NEW YORK STATE OF OPPORTUNITY. Department of Health

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May 31, 2023

To: Healthcare Providers, Clinical Laboratories, Commercial Laboratories, Hospitals, and Local Health Departments

From: New York State Department of Health (NYSDOH)
Wadsworth Center

Re: Implementation of a new *Mycobacterium tuberculosis* targeted next generation sequencing (tNGS) test for rapid detection of drug-resistance in respiratory specimens

Laboratory Notification:

Please distribute to:
Laboratory Directors, Laboratory Assistant Director, Laboratory Supervisors, Infection Preventionists, Medical Directors, Nursing Directors, Administrators, Hospital Epidemiologists, and Infectious Disease Physicians

Early detection methods are an essential part of tuberculosis (TB) testing algorithms to ensure that patients are placed on appropriate drug treatment regimens in a timely manner. New York State Department of Health's Wadsworth Center is excited to announce the implementation of a new test and a change in our testing algorithm that will improve our methods to detect drug resistance rapidly and accurately in *Mycobacterium tuberculosis* complex (MTBC). Wadsworth Center has developed and validated a multiplexed, targeted next generation sequencing (tNGS) assay that can predict drug resistance directly from clinical respiratory specimens. This assay will be performed on all respiratory specimens submitted that are MTBC PCR-positive meeting the criteria of the test.

This tNGS assay will rapidly provide sequence information for a greater number of loci than the current pyrosequencing assays, identifying specific mutations in 13 drug resistance-associated genes or loci in MTBC including: *rpoB, katG, inhA-mabA, oxyR-aphC, embB, embC-embA, pncA, gyrA, gyrB, ethA, rrs, rpsL* and *eis* implicated in resistance to first- and second-line MTBC antimicrobials (rifampin, isoniazid, ethambutol, pyrazinamide, fluoroquinolones, ethionamide, streptomycin, and kanamycin/amikacin). To date, the tNGS assay has resulted in an over two-week improvement in turnaround time when compared to whole genome sequencing (WGS), which requires an isolate. Additionally, the tNGS assay was found to be accurate and generated resistance prediction profiles highly concordant to those currently obtained with the existing WGS assay.

The tNGS assay will largely replace pyrosequencing in our current testing algorithm. WGS testing will still be performed on all MTBC culture-positive isolates for more comprehensive drug resistance prediction and for genotyping and surveillance to determine recent transmission.

CONTACT INFORMATION
For questions or further information, please contact Dr. Vincent Escuyer at Wadsworth Center at 518-474-4177.