Wisconsin State Laboratory of Hygiene
UNIVERSITY OF WISCONSIN–MADISON

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08/17/2026

To: WMLN laboratorians and Public Health partners

We are excited to announce that starting 08/31/2026, the Wisconsin State Laboratory of Hygiene (WSLH) will begin offering whole-genome sequencing (WGS) for species identification and first-line drug susceptibility testing for *Mycobacterium tuberculosis* complex (MTBC) isolates [MM00270]. This testing will supplement our current MTBC phenotypic First-Line Drug Susceptibility test [MM00204] and will be performed weekly. Phenotypic susceptibility testing will still be performed on all MTBC isolates for the foreseeable future.

The WSLH currently performs phenotypic drug susceptibility testing (pDST) for the standard first-line MTBC drugs isoniazid (INH), rifampin (RIF), ethambutol (EMB), and the fluoroquinolone moxifloxacin (MOX) (Note: phenotypic pyrazinamide (PZA) testing is still suspended due to manufacturer reagent issues). However, phenotypic susceptibility testing for MTBC drug resistance is one of the slowest processes in clinical diagnostic testing due to the slow growth of the MTBC organism. Obtaining results often takes more than 5 weeks from the point a specimen is collected and can be delayed further if the culture is contaminated or the patient MTBC organism is particularly slow growing. Use of molecular sequencing can identify potential resistances prior to phenotypic confirmation, allowing patients to be placed on a more reliable treatment regimen more quickly. Extensive work worldwide has allowed for a comprehensive understanding of mutations that contribute to drug resistance in MTBC[1]. This assay analyzes loci across the MTBC genome that have known contributions to drug resistance and searches these loci for mutations known with a high-level of confidence to contribute to MTBC drug resistance.

This testing will also allow the WSLH to report out species-level identification of the three MTBC organisms most commonly identified in WI residents: *M. tuberculosis*, *M. bovis*, and *M. bovis*-BCG (vaccine strain). Currently, WSLH reports all MTBC identifications only as *M. tuberculosis* complex; further speciation, particularly of *M. bovis* and *M. bovis*-BCG, have epidemiological and clinical implications due infection via uncommon pathways and intrinsic PZA drug resistance.

WGS will be performed on MTBC isolates identified at WSLH in primary clinical specimens, or any MTBC isolate identified at another clinical laboratory and referred to WSLH as part of the universal MTBC susceptibility and genotyping program currently in place. This testing will not be performed on isolates for which complete first-line susceptibility results have already been obtained. Where possible, species-level identification will be reported, along with predictions for INH, RIF, EMB, and PZA susceptibilities. Each drug will have an individual interpretation assigned based on whether mutations known to confer drug resistance were detected in genetic loci linked to MTBC drug resistance ("Mutations associated with resistance detected"), mutations of unknown significance ("Resistance cannot be ruled out"), or "No high-confidence resistance mutations detected". If sequence quality is low with too many uncalled bases, or there are other quality control issues that do not allow for a reliable prediction to be made, a "No Result" determination will be assigned. A draft test result is attached to this message.

This testing update will go live on 08/31/2026. This test is not orderable via WSLH requisition; WSLH TB microbiologists will automatically perform the testing on isolates that meet the testing criteria. This test is fee-exempt and test costs will be covered by the WI Department of Health.

Please let us know if you have any further questions or concerns!

Best,

Allen Bateman

Allen Bateman, PhD, MPH, D(ABMM)
Director, Communicable Disease Division

Contact for technical questions:
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1. World Health Organization (2023) *Catalogue of mutations in Mycobacterium tuberculosis complex and their association with drug resistance*. 2nd ed. Geneva: World Health Organization

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Laboratory Report

Allen Bateman, PhD, MPH, D(ABMM)
Communicable Disease Division Director

Errin C. Rider, PhD, D(ABMM),M(ASCP)CM, Director of Clinical Laboratory Services
Rudolph C. Johnson, PhD, WSLH Director

Submitted By:
Requested By:

Report Date:
8/19/2026

Patient: Zztest, Tb **Onset:** **WDPH Investigation #:**

DOB: 1/1/2000 **Sex:** **Address:**
Subm Pt #:

Specimen Details

	Collected	Type	Source	Submitter ID
25MM000007		Mycobacterial Isolate		

Mycobacteria Culture (Final result)

ID: 25MM000007 Type/Src: Mycobacterial Isolate

Mycobacteria Culture Result **Mycobacterium tuberculosis complex (A)**

Resulting Lab: WSLH

M. tuberculosis complex WGS (Edited)

ID: 25MM000007 Type/Src: Mycobacterial Isolate

	Result	Units
MTBC Identification	Mycobacterium tuberculosis	
Isoniazid DST Prediction	Mutation(s) associated with resistance to INH detected.	
Rifampin DST Prediction	Mutation(s) associated with resistance to RIF detected.	
Ethambutol DST Prediction	No high-confidence mutations associated with resistance to EMB have been detected.	
Pyrazinamide DST Prediction	No high-confidence mutations associated with resistance to PZA have been detected.	

Comments:
This next-generation sequencing-based test is designed for the identification and prediction of drug susceptibility in Mycobacterium tuberculosis complex (MTBC) isolates grown in MGIT broth. This test was developed and its performance characteristics determined by the Wisconsin State Laboratory of Hygiene, a Clinical Laboratory Improvement Amendments (CLIA) certified, high complexity clinical laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration.

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	Result	Units

This sequence-based prediction of drug susceptibility only identifies known mutations in common resistance-linked MTBC genetic loci. Novel mutations or potential contributions to drug resistance outside these regions will not be detected by this assay.

Phenotypic susceptibility testing is in progress.

Reportable Tests: **Mycobacteria Culture, M. tuberculosis complex WGS**

Resulting Labs

WSLH	WI STATE LAB OF HYGIENE-CDD, Madison WI

END OF REPORT