Wisconsin State Laboratory of Hygiene
UNIVERSITY OF WISCONSIN–MADISON

Communicable Disease Division
2601 Agriculture Drive, P.O. Box 7904
Madison, WI 53718
Phone: (800) 862-1013
Fax: (844) 390-6233• Web: www.slh.wisc.edu

5/23/25

Re: Phenotypic pyrazinamide testing for *Mycobacterium tuberculosis* suspended due to nationwide recall

This message is intended to notify all potentially affected parties that the WI State Laboratory of Hygiene (WSLH) will again be suspending phenotypic pyrazinamide (PZA) drug susceptibility testing for *Mycobacterium tuberculosis* complex (MTBC) isolates. As many of you may be aware, Becton, Dickinson and Company (BD), the manufacturer of the BD BACTEC™ MGIT™ reagents, has been experiencing quality issues with reagents included in the BACTEC™ MGIT™ 960 PZA kit (product 245128) for at least the last year. These quality issues have led to an increase in quality control failures and reports of increased PZA false-resistance observed for patient specimens.

This testing was previously discontinued at WSLH in July 2024 after notification from BD that they were initiating a nationwide recall of all available lots of the PZA test kit. WSLH reinstated testing in February 2025 after evaluating new lots of material produced after BD indicated the root cause of the false resistance had been identified and action taken to prevent recurrence. However, on May 20, 2025 WSLH received a second letter from BD once again instructing us to discard all currently available lots of PZA kits and to discontinue use immediately. The letter is attached to this message for distribution or your own records as needed.

Given this communication and instruction to discard testing kits, testing at WSLH is impacted, and effective immediately, we will again be suspending phenotypic PZA susceptibility testing. All *Mycobacterium tuberculosis* complex isolates received for first-line susceptibility testing during this suspension will have the PZA result noted as "not reported" and a comment will be added to the report stating that a nationwide recall is the reason this testing was not performed. Unfortunately, as this is a nationwide recall of this product, there is not currently a suitable alternative for phenotypic PZA testing. At this time, it is unknown when or if new product may be released. Until then, the WSLH will continue to test and report the other three first-line drugs (isoniazid, rifampin, and ethambutol).

The Centers for Disease Control and Prevention (CDC) have informed WSLH that they will continue to accept MTBC isolates for sequencing of the *pncA* gene, the most common site for PZA resistance mutations. However, the CDC has permanently discontinued their MTBC speciation testing. If *M. bovis* or *M. bovis*-BCG is strongly suspected and MTBC speciation would inform patient care, please reach out to the WSLH through the contact information below or through the WI Department of Health Services TB Program.

Sincerely,

Allen Bateman, PhD, MPH, D(ABMM)
Director, Communicable Disease Division
Wisconsin State Laboratory of Hygiene

Contact for technical questions:
Nate Simon
WI TB Program Laboratory Coordinator
Microbiologist III
Wisconsin State Lab of Hygiene
Nathan.simon@slh.wisc.edu
608-224-4265