## Oregon State Public Health Laboratory



May 23, 2025

Dear Colleagues,

On May 20, 2025, Becton, Dickinson and Company (BD) released an expansion of the <u>summer 2024 recall notice (pdf)</u> affecting the MGIT<sup>TM</sup> pyrazinamide (PZA) Kit used by the Oregon State Public Health Laboratory (OSPHL) for drug susceptibility testing. These test kits have been recalled because they "may intermittently produce falsely resistant results" for PZA on Mycobacterium tuberculosis (MTB) isolates.

## What the recall means for PZA susceptibility testing:

OSPHL is unable to provide PZA susceptibility testing results beginning May 20 due to the recall expansion. Until testing can be resumed, PZA results will be released as "Test Not Performed" with a comment describing the recall.

OSPHL will resume forwarding of all samples requiring PZA susceptibility testing to the CDC Division of TB Elimination (DTBE) Laboratory Branch for pncA molecular testing for PZA resistance. The CDC laboratory turnaround time to release results is approximately 5 weeks.

## What the expanded recall means for OSPHL results already released:

OSPHL resumed testing for PZA resistance in March 2025. During this time, our laboratory has not released any resistant results. Therefore, no OSPHL results are affected by the expanded recall.

Thank you for the dedication you put into caring for patients with MTB. Please do not hesitate to contact us with questions or concerns:

- Laboratory Technical: 503-693-4100
  - Matthew Burns, General Microbiology Section Manager matthew.c.burns@oha.oregon.gov
  - Lillian McLitus, Interim Tuberculosis Testing Lead lillian.mclitus@oha.oregon.gov

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- Clinical consultation regarding treatment regimen:
  - OHA TB Program 503-358-8516 or <a href="mailto:heidi.behm@oha.oregon.gov">heidi.behm@oha.oregon.gov</a>

Sincerely,

Patrick Luedtke, MD, MPH Clinical Lab Director, OSPHL Matthew Burns, MSc General Microbiology Manager, OSPHL