PUBLIC HEALTH DIVISION
Oregon State Public Health Laboratory
Kate Brown, Governor

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Dear OSPHL Clients,

The Oregon State Public Health Laboratory (OSPHL) is simultaneously implementing two *M. tuberculosis* (MTB) testing work flow changes that will affect the results you receive from our laboratory. The changes will be implemented with specimens received at the laboratory on November 1, 2018.

All changes are being made after consultation with and agreement from the State of Oregon Tuberculosis Program. The information provided below details the changes that will be implemented. The OSPHL Lab Test Menu will be updated closer to the implementation date at www.healthoregon.org/labtests.

Please share this information with your colleagues who may need this information. If your facility does not order MTB tests or interpret these results, you may disregard this message.

Change 1: Reduced PCR Identification for MTB Positive Patients

The OSPHL currently performs PCR identification on culture growth from every acid-fast bacilli (AFB)-positive specimen. This can result in up to fifteen PCR identification results for one patient.

Beginning November 1, 2018, the OSPHL will stop performing PCR identifications on culture growth from every specimen. Rather, staff will perform PCR identification only when:

a. The last specimen tested for the patient was more than 28 days ago,
b. Culture growth morphology is not consistent with a previous PCR identification, or
c. PCR identification is requested by a clinician.

Your organization will begin to receive fewer PCR Identifications on laboratory result reports. The OSPHL will continue to provide a culture result for every specimen to indicate whether or not AFB was isolated. A colony count will also continue to be provided when appropriate. When a PCR identification is not being performed due to this change, the result report will indicate that the bacterial growth is consistent with a previous and current PCR identification and will reference that result report for reference.
An algorithm detailing the process used to determine which specimens will be tested using PCR Identification is included as an attachment to this message.

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Change 2: Antibiotic Susceptibilities Testing Changes

The OSPHL currently performs susceptibility testing for each patient newly diagnosed with *M. tuberculosis* by culture. Testing also occurs at three-month intervals if the patient is not responding to therapy. Susceptibility testing is performed using two methods: 1) MGIT-based testing, and 2) an agar proportion method.

Beginning November 1, 2018, the OSPHL will eliminate MGIT-based rifampin (RIF), isoniazid (INH), and ethambutol (EMB) testing. MGIT-based pyrazinamide (PZA) testing will remain in place because PZA sensitivity cannot be assessed using the agar proportion method.

The MGIT-based method is typically considered less accurate, while the agar-based method is considered the "gold standard" for susceptibility results. Because agar-based results take longer than MGIT-based results, facilities and providers will receive weekly preliminary reports detailing the status of growth until the final result report is released approximately four weeks after receipt of specimen at the OSPHL.

In addition, the Centers for Disease Control and Prevention (CDC) recommended that the OSPHL eliminate one susceptibility testing method during program evaluation meetings. Other public health labs in the United States perform testing similarly to the OSPHL's revised testing plan.

Why are these changes being made?

The OSPHL recently conducted a time study to determine the true cost of performing laboratory services. Tuberculosis testing showed significant financial shortfalls. In response, the OSPHL and the State of Oregon Tuberculosis Program have agreed on these changes that will allow the programs to be better stewards of state funds without significant changes to patient care.

We hope this notice provides you with sufficient time to implement these changes in your facility and notify your colleagues. If you have questions, please contact Caitlin Miranda, Microbiologist, at 503-693-4100 or Caitlin.miranda@state.or.us.

Sincerely,

John Fontana, PhD, (HCLD) ABB
OSPHL Director

Heidi Behm, RN, MPH
State of Oregon TB Controller

Attachment: OSPHL AFB Positive PCR Identification Algorithm

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