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September 18, 2023

To All OSPHL Tuberculosis Testing Clients,

Beginning in mid-December, the Oregon State Public Health Laboratory (OSPHL) will need to close its Biosafety Level 3 (BSL-3) testing suite for an estimated five weeks for routine maintenance and equipment replacement. As a result, there will be a period of time when M. tuberculosis (MTB) specimens cannot be tested in our laboratory. OSPHL and the Washington State Public Health Laboratories (WSPHL) have long supported each other, backing up each other's testing through periods of maintenance and surge capacity. During the period of BSL-3 closure at OSPHL, specimens will be sent to WSPHL for testing.

All specimens for mycobacterial testing must first be sent to OSPHL; WSPHL will not accept these specimens directly from Oregon facilities or laboratories.

Please note that the dates detailed below are our current best estimates and may be modified based on project timelines. We will notify you if any of these dates change substantively.

Phase 0: Prior to October 16, 2023

All specimens received prior to this date will be tested and resulted by OSPHL using routine procedures.

Phase 1: Starting October 16, 2023

- Types of Tests: AFB Smear, GeneXpert, and PCR identification of AFB-positive isolates
- Testing Laboratory: OSPHL
- Types of Tests: Culture and Reflex Susceptibilities (RIF/INH/PZA/EMB¹)
- Testing Laboratory: WSPHL

Phase 2: Starting October 30, 2023

- Types of Tests: AFB Smear and GeneXpert
- Testing Laboratory: OSPHL
- Types of Tests: Culture, Susceptibilities (RIF/INH/PZA/EMB¹), and PCR identification of AFB-positive isolates
- Testing Laboratory: WSPHL

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¹ Rifampin (RIF), Isoniazid (INH), Pyrazinamide (PZA), Ethambutol (EMB)

Phase 3: Starting December 12, 2023

 All specimens and isolates for mycobacterial testing received at OSPHL will be forwarded to WSPHL. OSPHL will not perform any mycobacterial testing.

Phase 4: Mid-January 2024 (BSL-3 project completion)

- OSPHL resumes routine testing for all new specimens or isolates received
- WSPHL completes testing for any specimens or isolates received prior to BSL-3 project completion. Oregon submitters may receive results for cultures up to 9 weeks from specimen receipt at WSPHL.

Are there any testing differences between OSPHL and WSPHL?

WSPHL does not test for Ofloxacin (OFLOX) susceptibility in their first-line drug panel. While WSPHL is performing susceptibility testing, Oregon submitters will not receive OFLOX results. If OFLOX susceptibilities are needed for your patient, please contact Heidi Behm, Oregon TB Controller, at 503-358-8516 or heidi.behm@oha.oregon.gov, to discuss the possibility of submitting to CDC for further testing.

WSPHL incubates solid media (culture) for six weeks. OSPHL incubates solid media for up to nine weeks.

WSPHL uses the same multiplex PCR for culture growth organism identification as OSPHL. Oregon submitters will continue to receive PCR results for *M. tuberculosis* (MTB) and *M. avium* complex (MAC). WSPHL also uses the same methods for GeneXpert and standard reference methods for AFB smear and culture as OSPHL.

For additional details about WSPHL's testing methods, you may review the <u>WSPHL Lab Test Menu</u>.

While WSPHL is performing testing for Oregon patients:

- Do not batch specimens for submission. This will be more important than typical due to additional transit delays to WSPHL.
- Please anticipate result delays for all tests to accommodate specimen shipment to WSPHL and result processing. A descriptive table of turnaround times is provided at the end of this message.
- Results for testing performed by WSPHL will be sent to OSPHL and forwarded to submitting facilities. Results will be delivered through existing mechanisms (fax, electronic EHR interface, Copia, and ELR).
- We are currently exploring our available options for the format of results released by WSPHL to be shared with Oregon submitters. More information will be available at a later date.

What is a Biosafety Level 3 Suite? 2

Each Laboratory space is categorized into a biosafety level (BSL) based on factors including infectivity, severity of disease, transmissibility of pathogens, and nature of tests conducted. Most of the laboratory environment at OSPHL is classified as BSL-2. However, OSPHL also maintains a BSL-3 laboratory environment for pathogens that are transmitted through the respiratory route or have the potential to cause severe or life-threatening illnesses. This heightened containment level ensures the safe handling and testing of these higher-risk pathogens.

Questions?

We recognize you may have questions about this project and its impact on testing. Please join our **Q&A** session on Thursday, September 28 at 12:30pm-1:30pm:

- Join: https://www.zoomgov.com/j/1604286919?pwd=d0ZWNDJ5ays4WGxzellidUxVcFJGdz0
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- Phone: 669-254-5252 / Meeting ID: 160 428 6919 / Passcode: 837916
- One-tap mobile: +16692545252,,1604286919#

If you are not able to join or have additional questions, please do not hesitate to contact us:

- Laboratory Manager: Marisa Frieder, General Microbiology Section Manager 503-693-4139 or marisa.d.frieder@oha.oregon.gov
- Laboratory Technical: Caitlin Miranda, MTB Testing Lead 503-693-4100 or caitlin.miranda@oha.oregon.gov
- Laboratory Operational: Sarah King, Client Services Coordinator 971-217-3522 or sarah.m.king@oha.oregon.gov
- OHA Tuberculosis Program: 503-358-8516 or TB@odhsoha.oregon.gov

Non-MTB BSL-3 Down-Time Considerations

For all other specimens impacted by the BSL-3 closure, including specimens for BT or Select Agent rule-out, subsequent communications will be distributed specific to those sample submissions closer to the BSL-3 project start date.

We will continue to keep you updated as the BSL-3 modification project progresses. Thank you for your collaboration and understanding.

Sincerely,

Patrick Luedtke, MD, MPH Interim Laboratory Director

Marisa Frieder, PhD Manager, General Microbiology

Attachment:

 Estimated Turnaround Time for Results When Sent to Washington State Public Health Laboratory (WSPHL)

² Brief CDC Biosafety Level Training: https://www.cdc.gov/training/quicklearns/biosafety/

Estimated Turnaround Time for Results When Sent to Washington State Public Health Laboratory $(WSPHL)^3$

Test	OSPHL TAT	Estimate with send-out to WSPHL
AFB Smear	24 working hours	2-3 working days
GeneXpert	48 working hours	2-4 working days
PCR isolate identification	6 working days	8-10 working days
MGIT Susceptibilities ⁴	Within 3 weeks	Within 5 weeks
Liquid media culture	Within 6 weeks	Within 7 weeks
Solid media culture	Within 9 weeks	Within 8 weeks

³ TAT listed from date of receipt at OSPHL

⁴ WSPHL does not test for Ofloxacin (OFLOX).