September 12, 2016

Dear OSPHL Client,

The Oregon State Public Health Laboratory (OSPHL) is making changes to the HIV testing algorithm that will affect specimen submission criteria for HIV testing. The OSPHL currently performs HIV testing using a fourth generation enzyme immunoassay (EIA) test, with confirmation and differentiation using the Bio-Rad Multispot. Bio-Rad is discontinuing the Multispot test and replacing it with the Geenius. Therefore, the OSPHL is implementing the Bio-Rad Geenius™ HIV 1/2 Supplemental Assay in place of the Multispot.

The change to the Geenius requires that serum be pulled off the clot within 72 hours of specimen collection. The Lab Test Menu on the OSPHL website will be updated to incorporate these changes on the date of implementation.

The following changes will be effective for specimens received on November 1, 2016. Please begin considering the following changes for your facility.

Specimen Transport Times
Specimens on which the serum has not been removed from the clot will need to arrive at the OSPHL within 69 hours (3 days minus 3 hours) of specimen collection in order for the Geenius test to be used. The OSPHL Client Services Coordinator is conducting an analysis of transit times for HIV specimens and will be in contact with your facility if changes to your courier schedule are needed.

In addition, in order to support this requirement, the OSPHL will implement changes such that specimens can be processed on Saturdays to mitigate the number of Unsatisfactory specimens due to the revised time line.

HIV Testing Algorithm
If a specimen is received later than 69 hours (3 days minus 3 hours) after specimen collection, the OSPHL will run the HIV screening test (EIA) if testing can occur within 7 days of specimen collection. If the screening test is reactive, the laboratory result report will note the delay and request that a second specimen be collected in order to complete the testing.

In conjunction with this change, the OSPHL is implementing a second change to our HIV testing algorithm. Specimens that are reactive with the initial screening test (EIA) but are negative by the HIV-1/HIV-2 differentiation test (e.g. Geenius) will now be forwarded automatically for viral load testing unless there is an issue with the specimen that requires recollection. There is currently no charge for viral load testing.

An algorithm showing the testing process is provided at the end of this message.
Test Request Forms
Time of specimen collection will be required on Test Request Forms. We are revising these forms now. In the interim, you may add the time of collection next to the HIV order box.

Laboratory Result Reports (faxed or electronic)
If the HIV EIA result is reactive, the Geenius™ will be used for confirmation. You will therefore see a new test name listed on the result report.

For locations that receive electronic result messages, we will work with you and your vendor to ensure the test is properly built before implementation.

If you have questions about these changes, you may contact the OSPHL HIV testing staff at 503-693-4100 or our Client Services Coordinator, Sarah Humphrey, at 503-693-4124 or sarah.m.humphrey@state.or.us.

Sincerely,

Christianne Biggs, MS
Manager, Virology/Immunology

OSPHL HIV Testing Algorithm, effective November 1, 2016: