

LABSTRACT – October 2020

Syphilis, HTLV, HIV, Rubella IgG, Hepatitis A, B and C Serologic Testing Platform Update

Audience

Healthcare providers, public health units, hospital and community laboratories that order syphilis, HTLV, HIV, rubella IgG, hepatitis A, B and C serologic testing from Public Health Ontario's (PHO) laboratory.

Overview

Effective October 5, 2020:

- PHO's laboratory is upgrading the current testing platform used to perform serologic tests for syphilis, HTLV, HIV, rubella IgG, hepatitis A, B and C in human serum.

Background information

For many years, serologic tests for syphilis, HTLV, HIV, rubella IgG, hepatitis A, B and C in human serum at PHO's laboratory have routinely been performed using the chemiluminescent microparticle immunoassay (CMIA) on the Abbott Architect testing platform. Although this platform has been extremely reliable over the years, it has become outdated and is being replaced by newer technology.

What is changing?

On October 5 2020, PHO's laboratory will commence serologic testing for syphilis, HTLV, HIV, rubella IgG, hepatitis A, B and C in human serum using the chemiluminescent microparticle immunoassay (CMIA) on Abbott's new Alinity testing platform. The Alinity system is designed to simplify diagnostics, improve workflow and drive further operational efficiencies.

The test reference ranges and interpretations for the serology test results performed on the Alinity system are essentially identical to the Architect system and thus remain unchanged for all tests with the exception of the detection range for the Hepatitis B Surface Antibody assay (HBsAb). The detection interval for the Architect system is 2.50mIU/mL to 1000mIU/mL while the detection interval for the Alinity system is 2.00mIU/mL to 1000mIU/mL. The onboarding of the new Alinity system will occur incrementally across PHO Laboratory sites, therefore there will be a short period of time where either lower Limit of Quantification [LOQ] (i.e. <2.00 mIU/mL or <2.50 mIU/mL) may appear on laboratory reports. Regardless of which LOQ is used, the overall interpretation of the patient's hepatitis B immune status will remain unchanged as, either 'No evidence of immunity' when the Anti-HBs is < 10 mIU/mL or 'Evidence of immunity' when the Anti-HBs is \geq 10 mIU/mL.

In addition, PHO's laboratory will now be reporting a qualitative rubella IgG result (Reactive, Non-Reactive, or Indeterminate) with an Interpretation. We will no longer report the quantitative antibody result.

Test Requisition, Specimen Collection and Handling

- There are **no changes** to the test requisition, specimen collection and specimen handling.
- Refer to publichealthontario.ca/en/laboratory-services/test-requisitions for test requisitions and requisitions for specimen containers and supplies
- Refer to publichealthontario.ca/en/laboratory-services/test-information-index for detailed specimen collection instructions

Algorithms and Result Interpretation

- There are no changes to testing algorithms and result interpretations
- Refer to the test information index at publichealthontario.ca/en/laboratory-services/test-information-index for detailed test information

For further information

- Contact the PHO Laboratory Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at customerservicecentre@oahpp.ca
- For PHO Laboratory specimen collection information and previous Lababstracts, refer to publichealthontario.ca/Labs
- The current version of the PHO's General Test Requisition and other forms are available at publichealthontario.ca/Requisitions
- To subscribe to future Lababstracts, email lababstracts@oahpp.ca
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHO's Laboratory Customer Service Centre.



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