

Lababstract – November 2016

HIV Confirmatory Test: Geenius™ HIV-1/HIV-2 Differential Assay

Replacement of HIV-1 Western Blot with Geenius™ HIV-1/HIV-2 Differential Assay

To Health Care Providers:

Effective November 7, 2016, the Public Health Ontario Laboratory (PHOL) will replace its current confirmatory HIV-1 Western Blot Assay with the Geenius™ HIV-1/HIV-2 Differential Assay, approved by Health Canada. The Geenius™ HIV-1/HIV-2 Differential Assay is an immunochromatographic test for the confirmation and differentiation of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1, Group M and O) and Type 2 (HIV-2) in serum or plasma samples. The Geenius assay system utilizes an automated reader and software to distinguish between HIV-1 and HIV-2 antibodies. It is more specific than the Western Blot test in confirming the presence of antibodies to HIV-1 and HIV-2 in specimens found to be repeatedly reactive by the PHOL screening assay.

The Geenius™ HIV-1/HIV-2 Differential Assay offers several advantages over Western Blot confirmation:

- Earlier detection of antibodies soon after HIV infection
- Ability to differentiate HIV-1 antibodies from HIV-2 antibodies
- Fewer indeterminate and false negative results early in the course of HIV infection
- Improved turnaround time for final diagnosis

In addition, the use of the Geenius™ HIV-1/HIV-2 Differential Assay aligns PHOL's HIV testing algorithm with the US Centers for Disease Control and Prevention (CDC) recommended testing guidelines.

Specimen requirements:

For HIV diagnostic serology, the minimum volume required is 5.0 ml whole blood or 1.0 ml serum or plasma.

Results Interpretation:

The following table outlines the interpretation of results generated by the Geenius™ Confirmatory Software:

HIV-1 Result	HIV-2 Result	Assay Interpretation
Negative	Negative	HIV Negative
Positive	Negative	HIV-1 Positive
Positive	Indeterminate	HIV-1 Positive
Positive ¹	Positive ¹	HIV-2 Positive (with HIV-1 Cross-reaction) ¹ Or HIV Positive (Untypable) ^{1,2}
Indeterminate	Negative	HIV-1 Indeterminate
Indeterminate	Indeterminate	HIV Indeterminate
Negative	Indeterminate	HIV-2 Indeterminate ²
Negative	Positive	HIV-2 Positive
Indeterminate	Positive	HIV-2 Positive

Notes:

- 1. Interpretation of the results for these samples is based on the number of HIV1 and HIV2 envelope bands detected by the Geenius assay. In general, samples that are reactive for both HIV1 and HIV2 envelope bands indicate HIV2-infection but cannot exclude co-infection with HIV1.**
- 2. Specimen will be forwarded to the National Laboratory for HIV Reference Services (NLHRS) for further testing.**

For further information:

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at CustomerServiceCentre@oahpp.ca
- For PHOL specimen collection information and previous Lababstracts, refer to <http://www.publichealthontario.ca/Labs>
- The current version of the PHOL General Test Requisition and other forms are available at <http://www.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 PHOL Customer Service Centre.