

## LABSTRACT – October 2021

# HIV-1 RNA Viral Load Testing and Reporting Updates

## Audience

Healthcare providers who order HIV-1 RNA Viral Load testing.

## Overview

This lababstract is intended to provide the following updates to HIV-1 Viral Load testing that went live on August 30, 2021:

- Testing update and guidance for result interpretation.
- Update to HIV-1 Viral Load reporting.

## Background information

On August 30, 2021, Public Health Ontario (PHO) changed the testing platform for HIV-1 RNA viral load quantification from the Abbott RealTime HIV-1 Viral Load assay to the Roche cobas® HIV-1 assay on the Roche cobas® 6800/8800 system, which is slightly more sensitive. The manufacturer's reported limit of detection for the Abbott assay was ~40 copies/mL (lower limit of quantitation of 40 copies/mL), whereas the Roche cobas® assay is ~13.2 copies/mL (lower limit of quantitation of 20 copies/mL).

## Content

### Testing Update: Unexpected Increase in HIV-1 Viral Load

Shortly after implementation, PHO observed an unexpected increase in HIV-1 viral load positivity and increased viral load levels. Notably, some patients with a history of an undetectable or low viral load were now detected at >40 copies/mL or levels 1-2 logs higher. Upon investigation with the manufacturer, it was determined that the Roche cobas® assay is more sensitive than the Abbott assay due to the detection of proviral DNA, which is present in white blood cells found in the buffy coat. This increase in sensitivity has been observed by other users who have switched from the Abbott to the Roche platform for HIV-1 viral load testing. To reduce the detection of proviral DNA, PHO has implemented updates to specimen handling and processing (following the manufacturer's recommendations), which have resolved this issue. Any affected results during this transition period were retested and notified to the submitting healthcare provider.

**If for any reason you suspect that your patient's viral load is higher than expected based on the clinical situation**, please submit another specimen following recommended collection guidelines, or consult with a microbiologist at PHO. To ensure accurate results, it is important that specimens are collected following recommended guidelines found at [www.publichealthontario.ca/HIVViralLoad](http://www.publichealthontario.ca/HIVViralLoad). Specimens that are collected and/or processed outside the recommended guidelines will not be tested.

## Changes to HIV-1 Viral Load Reporting

### Detectable HIV-1 Viral Loads

As a result of the assay change, HIV-1 viral loads were being reported recently using scientific notation. Based on feedback from clients and to be consistent with the previous reporting, PHO has reverted to reporting detectable HIV-1 viral load as a whole number (e.g., 45,000 copies/mL).

Moving forward, please note that a true low-level viral load may now be detected using the more sensitive Roche cobas<sup>®</sup> assay, which was previously undetectable with the less sensitive assay (i.e., Abbott). **PHO encourages healthcare providers to reinforce messaging with patients that if their viral load level is <200 copies/mL, they are considered virally suppressed and unlikely to transmit HIV to others.**

### Viral Loads 20 to <40 copies/mL

Due to the decreased lower limit of quantitation for the Roche cobas<sup>®</sup> assay, viral loads that were previously detected at 20 to <40 copies/mL and reported as <40 copies/mL using the Abbott assay will now be reported as an absolute value (e.g. 30 copies/mL). **Generally, no change in clinical management is recommended for viral loads <40 copies/mL**; however, viral loads should be interpreted based on the patient's clinical context.

For further clinical guidance, please consult an HIV specialist and/or refer to the following clinical care guidelines:

- Ontario Clinical Care Guidelines: [occguidelines.com/guidelines/](http://occguidelines.com/guidelines/)
- NIH Clinical Guidelines: [clinicalinfo.hiv.gov/en/guidelines](http://clinicalinfo.hiv.gov/en/guidelines)

If you have additional questions or would like to speak to a microbiologist at PHO, please contact PHO Laboratory's Customer Service Center at the contact details below.

## For further information

- Contact the PHO's Laboratory Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at [customerservicecentre@oahpp.ca](mailto:customerservicecentre@oahpp.ca)
- For PHO's Laboratory specimen collection information and previous Lababstracts, refer to [publichealthontario.ca/test\\_directory](http://publichealthontario.ca/test_directory)
- The current versions of the PHO Test Requisition and other forms are available at [publichealthontario.ca/Requisitions](http://publichealthontario.ca/Requisitions)

- To subscribe to receive future Labstracts, [register on our website](#)
- 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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