

**Date:** December 14, 2012

**To:** Alberta Health, Infectious Diseases physicians, Medical Officers of Health, Alberta MicroNet, Laboratory Directors and Managers

**From:** Provincial Laboratory for Public Health (ProvLab)

**Re:** Transitioning of platforms/assays for HIV viral load testing to the Abbott RealTime HIV-1 assay

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**Key Message:**

- **Effective January 7, 2013**, Human Immunodeficiency Virus (HIV) viral load testing performed at ProvLab will be transitioned to the Abbott RealTime HIV-1 assay on the M2000.
- Due to the development of newer and more efficient testing technologies, this new platform will ensure a more accurate and reliable quantitation of HIV-1 RNA for patient management, particularly at the lower viral load ranges.
- All validation requirements for the new assay have now been completed.

**Why is this important:**

- Specific concerns about the performance of certain commercially available assays with PPT plasma tubes transported from remote sites have been addressed with the switch to this new platform.
- During the validation testing, it was noticed that the Abbott RealTime HIV-1 assay did read a little lower than the currently used commercial assay – between 0.3-0.5 log<sub>10</sub> lower over the range 10<sup>2</sup>-10<sup>5</sup> copies/mL. We believe that this lower reading may be more accurate because it is not detecting any additional integrated HIV-1 proviral DNA, which is not relevant to the monitoring of response to antiretroviral therapy.
- The lower limit of quantifiable detection for the Abbott RealTime HIV-1 assay is 40 copies/mL. This is slightly higher than the previously used commercial assay, which had a cut-off of 20 copies/mL. Please take this into consideration when reviewing your patient's management. We believe that the other benefits of this new assay outweigh this slight increase in the cut-off value.

**Sample types:**

- There will be no change in the required sample type. Both EDTA and PPT plasma tubes can be used for the new Abbott RealTime HIV-1 assay.
- All other previous requirements regarding the submission of specimens for molecular tests still apply.

**Result reporting:**

- There will be no change to result reporting. Results will continue to be reported in copies/mL.

**Inquiries and feedback may be directed to:**

- Dr. Julian Tang, Virologist, ProvLab at: 780-407-3068 or E-mail: [Julian.tang@albertahealthservices.ca](mailto:Julian.tang@albertahealthservices.ca)
- Edmonton Site – Phone: 780-407-7121 (ask for the Virologist-on-Call)
- Calgary Site – Phone: 403-944-1200 (ask for the Virologist-on-Call)

**This bulletin has been reviewed and approved by:**

Dr. Graham Tipples, Medical / Scientific Director, Provincial Laboratory for Public Health (ProvLab)