
Date: April 9, 2013

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

From: Provincial Laboratory for Public Health (ProvLab)

Re: Transitioning of Platforms/Assays for HBV Viral Load Testing to the Abbott RealTime HBV Assay

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Key Messages:

- **Effective April 15, 2013**, Hepatitis B Virus (HBV) viral load (VL) testing performed at ProvLab will be transitioned to the Abbott RealTime HBV 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 HBV DNA for patient management. This is particularly noticeable at the lower viral load ranges (<100 IU/mL).
- In addition, there is an extra log₁₀ of accurate quantitation – up to 10⁹ IU/mL with this new assay.
- All validation requirements for the new assay have now been completed.

Why this is important:

- The more linear calibration method of the new Abbott M2000 HBV VL assay will reduce inter-assay and inter-sample variation, thereby making consecutive sample viral loads more reliably correlated for individual patients.
- The wider, accurately quantifiable range of the new assay (10¹ to 10⁹ IU/mL) will enhance the assessment of virological response at the various required time-points for monitoring patients on therapy.

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 HBV assay. Please send at least 4 mL's of blood, whichever tube type is used, for testing.
- All other previous requirements regarding the submission of specimens for molecular tests still apply (see <http://www.provlab.ab.ca/guide-to-services.pdf>).

Result reporting:

- Results will continue to be reported in IU/mL,
- Generally, the HBV VL results from the new assay appear to match those from the previous assay quite closely. The results from the new assay can be used as reported for the continuing care of patients on therapy during this transition period, i.e. no conversion factor is required.

Inquiries and feedback may be directed to:

- Dr. Julian Tang, Virologist, ProvLab at: 780-407-3068 or E-mail: 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)