Laboratory Bulletin

Date: **March 5, 2013**

To: **Alberta Health, Alberta MicroNet, Hepatologists / Gastroenterologists, Infectious Diseases Physicians, Infection Prevention and Control, Medical Officers of Health, Transplant Physicians, Program Directors and Coordinators, Laboratory Directors and Managers**

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

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

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message:

- ***Effective March 14, 2013***, Hepatitis C Virus (HCV) viral load testing performed at ProvLab will be transitioned to the Abbott RealTime HCV 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 HCV RNA for patient management, particularly at the lower viral load ranges.
- All validation requirements for the new assay have now been completed.

Why this is important:

- Previously, turnaround times for HCV viral load (VL) testing have occasionally been longer than expected due to confusion about whether an HCV quantitative or qualitative result is required. With the new assay, all results will be quantitative, i.e. the qualitative option will no longer be available. So this source of confusion and delayed testing will no longer be an issue.
- The more linear calibration method of the new Abbott M2000 HCV VL assay will reduce inter-assay and inter-sample variation, thereby making consecutive sample viral loads more reliably correlated.
- The improved limit of detection for the new assay (12 IU/mL versus the previous 43 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 HCV VL assay, as well as the usual serum tubes. 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.
- However, note that because of the more linear and less variable calibration method used by the new assay, there will be a noticeable ~3-fold drop in HCV VL when compared to the previous assay. Please use this conversion factor for patients transitioning between these two assays in your care. This conversion factor should also apply to the checkpoint cut-offs for the new drugs: telaprevir (reducing the 1000 IU/mL threshold down to ~ 300 IU/mL) and boceprevir (reducing the 100 IU/mL threshold down to ~30 IU/mL), both of which are reliably within the quantitative range of this new assay.

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)