

---

**Date:** January 23, 2013

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

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

**Re:** Transitioning of Platforms/Assays for HCV Genotyping to the Abbott RealTime HCV Genotype II

---

**PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE**

---

**Key Messages:**

- **Effective January 28, 2013**, Hepatitis C virus (HCV) genotyping performed at ProvLab will be transitioned to the Abbott RealTime HCV Genotype II assay on the M2000.
- Due to the development of newer and more efficient testing technologies, this new platform will ensure a quicker, more sensitive and accurate determination of the HCV genotype, particularly of HCV genotypes 1a and 1b.
- All validation requirements for the new assay for the most common HCV genotypes in this Alberta population have now been completed.

**Why this is important:**

- Optimal outcomes for the use of the new protease inhibitor drugs (telaprevir and boceprevir) depend to some extent on their sub-genotype status (1a or 1b). The distinction between sub-genotypes 1a and 1b is even more important for other direct acting anti-HCV drugs in development. This new assay includes an NS5B target of the HCV genome which can more reliably distinguish between these two different HCV sub-genotypes.
- During validation testing, it was found that the new assay is very sensitive - it can reliably determine the HCV genotype in samples with HCV viral loads as low as 500 IU/mL and even lower than this.
- The assay also has a relatively short turnaround time, so the HCV genotyping results can be reported out at least once a week (depending on the batch sizes), which will allow clinical teams to start their patients on therapy, earlier, if required.
- Currently, the validation of this assay has been completed for HCV genotypes 1a, 1b, 2, 3 and 4. The validation for genotypes 5 and 6 have not yet been completed, but these genotypes are rare in Alberta, and the validation of this assay for these genotypes will be completed in due course.
- Hence this new assay is now available for HCV genotypes 1-4. Any HCV genotype 5 or 6 results that occur will be discussed with the requesting physicians, including the need for any additional samples for further testing.
- Occasionally, the assay will report some cross-reactivity between two different genotypes, and further samples for additional testing may be requested to clarify which genotype is predominant. These individual cases will be discussed with the patient's clinical teams, as required.

**Sample types:**

- Both EDTA/ PPT plasma and serum tubes can be used for the new Abbott RealTime HCV Genotype II assay. Please send at least 4 mL of whole blood in these tubes for testing to allow sufficient plasma/serum for testing, otherwise results may be delayed. Please note that if you also require an HCV viral load test, two tubes of this volume will be required.
- All other previous requirements regarding the submission of specimens for molecular tests still apply.

**Result reporting:**

- Results will be reported as HCV genotypes 1a, 1b, 2, 3 or 4, and very occasionally, mixtures of more than one genotype if this is confirmed on repeat testing.

**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)