

Labstract May 2013

Hepatitis C Virus (HCV) Genotype/Subtype Testing

Change in Testing Methodology

To Health Care Providers:

Effective July 1, 2013, the Public Health Ontario Laboratories (PHOL) will replace its current Hepatitis C Virus Genotype Invader Assay with the Abbott RealTime HCV Genotype II assay. The new assay utilizes the m2000 automated system. It is an in vitro reverse transcription – polymerase chain reaction (RT-PCR) assay for determining the genotype(s) of hepatitis C virus in plasma and serum from HCV- infected individuals.

As with the previous test, the Abbott RealTime HCV Genotype II assay detects genotypes 1, 2,3,4,5 and 6. The main difference between the two assays is that the Abbott RealTime HCV Genotype II can differentiate between subtypes 1a and 1b.

The Limit of Detection (LOD) is defined as the HCV RNA concentration detected and HCV genotype accurately identified with a probability of 95% or greater. The LOD claim of the Abbott RealTime HCV Genotype II assay is 500 IU/mL when there is a perfect match between the relevant assay primers/probe and the specimen nucleotide sequence. According to the manufacturer, the accuracy of the assay when compared to nucleotide sequencing is 98.28% for the overall genotype comparison, 97.27% for the subtype 1a comparison and 96.55% for the subtype 1b comparison.

Background Information:

Genotyping/subtyping of HCV is useful in evaluating the likelihood of response to currently available antiviral therapy. The HCV genotype/subtype is a major factor in determining the length and success of treatment for HCV as each genotype/subtype has a specific response to hepatic drug therapy. Patients with HCV genotypes 2 or 3 generally respond better to therapy and typically require approximately 24 weeks of treatment. Patients with HCV genotypes 1 and 4 to 6 may require up to 48 weeks of treatment. Due to the advent of new drugs for hepatic drug therapy there has been an increased demand for HCV subtyping.

Criteria for HCV Genotyping/Subtyping Testing:

- Consideration for treatment with ≥ 500 IU/mL HCV RNA viral load
- First pre-treatment (i.e. baseline) sample submitted for HCV RNA viral load
- Reinfection or reexposure cases

HCV Genotyping/Subtyping – Change in testing methodology (Continued)

Specimen Requirements:

- A minimum 1.5 mL of frozen serum or plasma separated within 6 hours of collection is required for testing. If HCV RNA viral load testing is required provide an additional 2.5 mL of frozen serum or plasma.
- Ship specimens frozen on ice packs or dry ice.
- All requests for HCV genotyping/subtyping must include a completed PHOL Requisition Form or a Laboratory Information Form (F-C-HE-036)

Results Interpretation:

The following table is a guide to aid in the interpretation of HCV Genotype/Subtype results. It is important to note that other mixed genotype results or cross reactivity results not found in the table below will be reported by the assay software.

Result	Interpretation
NOT DETECTED	The assay did not detect the HCV genotype/subtype. Specimen to be forwarded to the reference laboratory for further testing.
Hepatitis C Genotype Type (1-6)	The assay detected one of the 6 HCV genotypes
Hepatitis C Genotype 1a	The assay detected HCV genotype 1 and subtype a
Hepatitis C Genotype 1	The assay detected HCV genotype 1 but could not provide a subtype result. Specimen to be forwarded to the reference laboratory for further testing.
Hepatitis C Genotype 1a,4	The assay detected mixed HCV genotypes 1a and 4
Hepatitis C Genotype 1a reactivity with 4	The assay detected HCV genotype 1a with cross-reactivity with HCV Genotype 4
Hepatitis C Genotype Indeterminate	The assay detected HCV but could not provide a genotype/subtype result. Specimen to be forwarded to the reference laboratory for further testing.

NB: Any result of further testing from the reference laboratory will be forwarded when received.

Turnaround time

Results will be available within 10 working days of receipt of the specimen at PHOL except for specimens forwarded to the reference laboratory for further testing.

For further information:

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free) or by email at CustomerServiceCentre@oahpp.ca
- For the PHOL Specimen Collection Guide and previous Lababstracts, refer to <http://www.oahpp.ca/services/public-health-laboratories.html>
- The current version of the PHO laboratory requisition form is available at <http://www.oahpp.ca/resources/requisitions.html>
- To subscribe to future Lababstracts, email lababstracts@oahpp.ca