

Labstract – May 2018

Hepatitis C Virus (HCV) RNA and Genotype Testing and Interpretation - Update

Audience

Healthcare providers who test patients for Hepatitis C (HCV) infection

Overview

Effective May 2018:

- Public Health Ontario's laboratory (PHOL) is changing the hepatitis C real-time PCR (RT-PCR) assay system that it currently uses (Roche Cobas Ampliprep/Cobas Taqman 96) to the Roche Cobas 6800 for the detection and quantification of hepatitis C virus (HCV RNA) in human serum or plasma.
- The performance characteristics of the new assay will not have an impact on detecting HCV RNA and results will be reported the same way (Table 1).
- This document will provide information about the HCV RNA and Genotype testing performed at PHOL for disease and treatment monitoring.

Background

1. Hepatitis C RNA Testing

HCV RNA testing should not be used as a diagnostic test for diagnosing hepatitis C infection. It is most commonly used for measuring viremia (i.e., amount of virus in the blood) in patients who are HCV-antibody positive or when assessing patients with inconclusive HCV-antibody results. HCV RNA should be ordered at the following times and/or for the following indications:

1. As a baseline after a positive HCV-antibody result in order to determine the infectious status of the patient
2. Prior to and during antiviral treatment for hepatitis C
3. Post-treatment to determine if the patient has cleared the virus and achieved a sustained virologic response (SVR)

4. During the assessment and investigation of immuno-compromised HCV-antibody negative individuals
5. Follow-up of children between the ages of 6 weeks and 18 months of age who were born to HCV positive mothers.

Table 1: The following table is a guide to aid in the interpretation of HCV RNA results:

HCV RNA Result	Interpretation	Comments
Detected	Hepatitis C RNA detected, ≥ 15 IU/ml	Quantitative Viral Load will be provided
Detected	Hepatitis C RNA detected, < 15 IU/ml	The result for HCV RNA is below the linear range of the assay and thus the exact value cannot be calculated
Not Detected	No detectable Hepatitis C RNA	Refer to comments on laboratory report if follow-up testing is required

2. Hepatitis C Genotype

For patients with a detectable HCV RNA, genotyping of their HCV may be useful in evaluating the likelihood of response to some currently available anti-viral therapies and for epidemiologic purposes. However, with currently available direct acting anti-HCV therapies, the utility of genotyping has become less important for choosing a treatment regimen or for determining the duration of therapy.

Refer to [LAB-SD-092, Hepatitis C Virus \(HCV\) Genotype/Subtype Testing](#), available at www.publichealthontario.ca/lababstracts for current assay, Abbott RealTime HCV Genotype II.

Specimen Requirements

- A minimum of 2.5 ml of frozen serum or plasma prepared within 6 hours of blood collection is required. Samples received with less than 2.5 ml will be rejected.
- Detailed collection instructions are available at www.publichealthontario.ca/test_directory.
- If collection of serum or plasma is difficult to collect, Dried Blood Spots (DBS) can be collected by according to the instructions in [LAB-SD-123 Hepatitis C Virus \(RNA\) detection in Dried Blood Spots \(DBS\)](#).
- No additional sample is usually required for HCV genotyping. The first pre-treatment (i.e. baseline) sample submitted for HCV RNA testing will be automatically used to perform HCV genotyping if the HCV Viral load is ≥ 500 IU/mL. Below this level, HCV genotyping cannot be performed.

Requisition

All requests for testing must include a completed [Hepatitis PCR Requisition: Hepatitis C RNA and /or Hepatitis B DNA Viral Load](#) available at www.publichealthontario.ca/requisitions

Reference:

Product Insert – Cobas HCV Quantitative nucleic acid test for use on the Cobas 6800/8800 Systems.
January 2017

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 PHOL specimen collection information and previous Lababstracts, refer to <http://www.publichealthontario.ca/Labs>
- The current version of the PHOL General Test Requisition and other forms are available at <http://www.publichealthontario.ca/Requisitions>
- To subscribe to future Lababstracts, [register on our website](#)
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHOL Customer Service Centre.