Public Health Ontario | Santé publique Ontario

LABSTRACT – Released January 2008, Updated December 2019

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

Audience

Healthcare providers who order hepatitis C virus (HCV) RNA for monitoring and treatment purposes.

Overview

- Public Health Ontario (PHO) Laboratory uses Roche Cobas 6800 for the detection and quantification of HCV RNA in human serum or plasma.
- Reporting of results has changed as summarized in Table 1.
- This document will provide information about the HCV RNA and Genotype testing performed at PHO Laboratory for disease and treatment monitoring.

Background information

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.

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Results Interpretation

Table 1: The following table is a guide for the interpretation of HCV RNA results:

Hepatitis C RNA Viral Load Reported Result	Interpretation
Target Not Detected	HCV RNA Not Detected
<1.50E+1 IU/mL	HCV RNA detected below the linear range of the assay. Unable to quantify. (Note: The result for HCV RNA is below the linear range of the assay which is 15 IU/mL and thus the exact value cannot be calculated)
≥1.50E+1 to ≤ 1.00E+8 IU/mL	Viral Load will be provided
>1.00E+8 IU/mL	HCV RNA detected above the linear range of the assay. Unable to quantify. (Note: The result for HCV RNA is above the linear range of the assay which is 1.00E+8 IU/mL and thus the exact value cannot be calculated)

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 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 publichealthontario.ca/test_directory
- If collection of serum or plasma is difficult to collect, Dried Blood Spots (DBS) can be collected 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

References

Roche Molecular Systems. cobas® HCV: quantitative nucleic acid test for use on the cobas® 6800/8800 systems. 07767692001-01EN. Doc Rev 1.0. Laval, QC: Roche Molecular Systems; c2017.

For further information

- Contact the PHO Laboratory Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at customerservicecentre@oahpp.ca
- For PHO Laboratory specimen collection information and previous Labstracts, refer to publichealthontario.ca/test directory
- The current version of the PHO Laboratory General Test Requisition and other forms are available at publichealthontario.ca/Requisitions
- To subscribe to future Labstracts, 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 PHO Laboratory Customer Service Centre.