Labstract – April 2017

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

Audience

Healthcare providers who treat patients with Hepatitis C infection

Overview

This document provides information on Hepatitis C Viral Load and Genotype testing at Public Health Ontario Laboratory (PHOL).

Background

PHOL is currently using the Roche Taqman Real Time HCV RNA PCR assay which has a linear range of 15 IU/ml to 10 E+8 IU/ml, for Hepatitis C RNA testing.

1. Hepatitis C RNA Testing

Clinical Utility

Quantitation of HCV RNA by PCR is used to measure viremia in HCV-antibody positive individuals at the following times: 1) Prior to starting anti-viral treatment (i.e., baseline), 2) During anti-viral treatment, and 3) Post-treatment to determine if they have achieved a sustained virologic response (SVR). Detection of HCV RNA may also be used to assess active HCV infection in immuno-compromised HCV-antibody negative individuals.

Specimen Requirements

A minimum of 2.5 ml of frozen serum or plasma is required to perform the Roche Taqman HCV RNA assay. Samples received with less than 2.5 ml will be rejected. All requests for HCV RNA testing must include a completed Hepatitis PCR Requisition: Hepatitis C RNA and /or Hepatitis B DNA Viral Load available at www.publichealthontario.ca/requisitions

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Results Interpretation

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	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

Clinical Utility

Genotyping of HCV may be useful in evaluating the likelihood of response to currently available anti-viral therapy 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/labstracts for current assay, Abbott RealTime HCV Genotype ll.

Specimen Requirements

No additional sample is required HCV genotyping. The first pre-treatment (i.e. baseline) sample submitted for HCV RNA will be automatically used to perform HCV genotyping.

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 Labstracts, 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 Labstracts, email labstracts@oahpp.ca
- 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.