

LABSTRACT - MAY 2022

Hepatitis C Virus (HCV) Genotype/Subtype Testing – Change in Testing Platform

Audience

Healthcare providers who order Hepatitis C virus (HCV) RNA viral load and genotype/subtype testing.

Overview

Effective May 2, 2022, Public Health Ontario's (PHO) laboratory will replace its current Abbott Real-Time HCV Genotype II assay on the Abbott m2000 automated system with the Roche cobas® HCV GT assay on the cobas® 4800 system. The assay change is the result of competitive procurement and technical evaluation.

As with the previous assay, the Roche cobas® HCV GT assay detects genotypes 1 (including subtypes a and b) to 6 in human serum.

Highlights of changes:

1. Update to the limit of detection (LOD)

The LOD of the cobas® HCV GT is 50 IU/mL for genotype 2, 125 IU/mL for genotypes 1a, 1b, 3, 4, and 6 and 500 IU/mL for genotype 5.

2. Update to the specimen collection

Whole blood collected in serum separator tubes (SST) may be stored and/or transported for up to 24 hours at 2°C to 25°C before serum separation. Separated serum may be stored in secondary tubes for up to 24 hours at 2°C to 25°C, up to 72 hours at 2°C to 8°C, or up to 6 weeks at \leq -18°C.

3. Update to minimum HCV RNA viral load required for HCV genotyping

HCV specimens must have a detectable viral load of **at least 125 IU/mL** for HCV genotyping to be performed. HCV genotype 5 is relatively uncommon in Canada; however, it may be missed in specimens with a viral load <500 IU/mL. As per our current algorithm, the first pre-treatment (baseline) specimen submitted for HCV RNA viral load testing will be automatically tested for HCV genotype if it meets the minimum viral load requirement.

For more details and the most up-to-date information on HCV genotyping at PHO, including testing indications, collection and submission guidance, and testing algorithm, please refer to PHO's Hepatitis C Genotyping/Subtyping Test Information Sheet.

For further information

- Contact PHO's Laboratory Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at customerservicecentre@oahpp.ca
- For PHO's Laboratory specimen collection information and previous Labstracts, refer to: <u>www.publichealthontario.ca/en/Laboratory-Services/Test-Information-Index</u>
- The current versions of the PHO Test Requisition and other forms are available at: www.publichealthontario.ca/en/laboratory-services/test-requisitions
- To subscribe to receive 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's Laboratory Customer Service Centre.



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