

Labstrack – May 2018

Hepatitis B Virus DNA (HBV DNA) Testing and Interpretation - Update

Audience

Health care providers who order hepatitis B DNA testing for monitoring and treatment purposes.

Overview

Effective May 2018:

- Public Health Ontario's laboratory (PHOL) is changing the hepatitis B 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 B virus (HBV DNA) in human serum or plasma.
- The lower limit of detection will change from 20 IU/ml to 10 IU/ml. Refer to Table 1 for HBV DNA results and interpretation.
- The performance characteristics of the new assay will not have an impact on detection of HBV DNA.
- This document provides information about the HBV DNA testing performed at PHOL for disease and treatment monitoring.

Background Information

HBV DNA testing should not be used as a diagnostic test for hepatitis B infection and should only be ordered in those with a confirmed HBV infection based on serologic testing. Current management guidelines recommend that patients infected with hepatitis B should have their HBV DNA level measured at baseline (i.e., prior to starting therapy) and at three to six month intervals while receiving antiviral therapy. More frequent testing may be indicated for those patients suspected of having developed resistance to their antiviral therapy. Although there may be other clinical indications for requesting an HBV DNA test (e.g. a patient in whom the only marker of infection is a positive HBcAb test), routine monitoring of HBV-infected patients who are not on treatment or being considered for treatment is not recommended.

Results Interpretation

Table 1: The following table is a guide for the interpretation of HBV DNA results:

HBV DNA Result	Interpretation	Comments
Detected	Hepatitis B DNA detected, ≥ 10 IU/ml	Quantitative viral load will be provided
Detected	Hepatitis B DNA detected, < 10 IU/ml	The result for HBV DNA is below the linear range of the assay and thus the exact value cannot be calculated and therefore cannot be provided
Not Detected	No detectable hepatitis B DNA	Refer to comments on laboratory report if follow-up testing is required

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.

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 HBV 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.