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LABSTRACT – Released January 2008, Updated December 2019

Hepatitis B Virus DNA (HBV DNA) Testing and Interpretation

Audience

Health care providers who order hepatitis B virus (HBV) DNA testing for monitoring and treatment purposes.

Overview

- Public Health Ontario (PHO) Laboratory uses the Roche Cobas 6800 for the detection and quantification of HBV DNA in human serum or plasma.
- The reporting ranges for HBV DNA has changed. Refer to Table 1 for HBV DNA results and interpretations.

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 clinical 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.

Content

Results Interpretation

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

Hepatitis B DNA Viral Load Reported Result	Interpretation
Target Not Detected	HBV DNA Not Detected
<1.00E+1 IU/mL	HBV DNA detected below the linear range of the assay. Unable to quantify. (Note: The result for HBV DNA is below the linear range of the assay which is 10 IU/mL and thus the exact value cannot be calculated)
≥1.00E+1 to ≤ 1.00E+9 IU/mL	Viral Load will be provided
>1.00E+9 IU/mL	HBV DNA detected above the linear range of the assay. Unable to quantify. (Note: The result for HBV DNA is above the linear range of the assay which is 1.00E+9 IU/mL and thus the exact value cannot be calculated)

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

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

References

Roche Molecular Systems. cobas® HBV: quantitative nucleic acid test for use on the cobas® 6800/8800 systems. 08122938001-01EN. 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.