

February 2008

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

To Health Care Providers

For HBV DNA testing, the Ontario Public Health Laboratory (OPHL) has replaced the Cobas Amplicor Quantitative (Research Use Only) HBV DNA assay with the Roche Taqman Real Time HBV DNA PCR assay. The linear range of the new Roche Taqman HBV DNA assay is 12 IU/ml to 10 E+8 IU/ml. In comparison, the linear range of the previously used Cobas Amplicor Quantitative HBV DNA assay was only 60 IU/ml to 10 E+6 IU/ml.

Clinical Utility

HBV DNA levels are indicated for anti-viral monitoring, this test should not be used as a diagnostic test for a Hepatitis B infection. Based on current guidelines, 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 anti-viral therapy. More frequent testing may be indicated for those patients suspected of having developed resistance to their anti-viral medication.

Specimen Requirements

A minimum of 2.5 ml of frozen serum or plasma is required to perform the Roche Taqman HBV DNA assay. Samples received with less than 2.5 ml will be rejected. All requests for HBV DNA testing must include a completed OPHL Test Requisition Form and a Laboratory Information Form, (F-C-HE-036) available at:
<http://www.health.gov.on.ca/english/providers/pub/labs/specimen.html>.

Results Interpretation

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

| HBV DNA Result | Interpretation | Comments |
|----------------|-------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Detected | Hepatitis B DNA detected, >12 IU/ml | Viral Load will be provided |
| Detected | Hepatitis B DNA detected, <12 IU/ml | The result for HBV DNA is below the linear range of the assay and thus the exact value cannot be calculated |
| Not Detected | No detectable Hepatitis B DNA | Refer to comments on laboratory report if follow-up testing is required |

\Hepatitis B Virus (HBV) DNA Testing and Interpretation – Update (continued)

For Further Information:

- Refer to the Specimen Collection Guide at www.health.gov.on.ca/english/providers/pub/labs/specimen.html
- Hepatitis Laboratory at (416) 235-5737
- OPHL HELPLINE at 1-800-640-7221