



Newfoundland & Labrador

PROVINCIAL PUBLIC HEALTH LABORATORY NETWORK

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MEMORANDUM

TO: All Physicians who treat HBV infection or health care providers who are co-managing an HBV infected patient with an HBV treatment specialist

RE: Change to the Hepatitis B Viral Load Testing

FROM: NL Provincial Public Health Microbiology Laboratory (NL PHML)

DATE: April 15, 2019

Dear Colleagues,

Hepatitis B virus (HBV) viral load (VL) requests were referred to the National Microbiology Laboratory (NML) where the Roche COBAS TaqMan assay/platform were used. Effective March 2019, NML has discontinued this service.

Effective April 2019, all the HBV VL requests will instead be referred to the Ontario Public Health Laboratory (OPHL). The OPHL uses a newer generation Roche® assay/platform for the detection and quantification of HBV DNA in human serum or plasma. In comparison to the NML assay, the only noticeable difference for the end users is a lower limit of detection (LLOD) - 10 instead of 20 IU/mL.

Indication for HBV VL testing:

HBV DNA VL is for monitoring those with confirmed HBV infection, and is **NOT** to be used as a diagnostic test. Other clinical indications for requesting an HBV DNA test or routine monitoring of HBV-infected patients who are NOT on treatment or are being considered for treatment will only be done in specific clinical circumstances that require review and approval by the PHML MOC. Providing clinical history on the requisition including whether the patient is on HBV therapy will avoid testing delays.

Impact of the change:

- Performance characteristics of the new assay are comparable
- There will be no change in the test requisition, sample collection, and result reporting method except the LLOD will be 10IU/mL

Any questions can be directed to the Office of the Director, PHML at 709 777 7233.

Thank you for your attention and cooperation.

George Zahariadis MD, FRCPC

Director and Chief, PHML

