

MEMORANDUM

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TO: Capital Health and Nova Scotia District Labs, Physicians, Clinics

FROM: Dr. Todd Hatchette / Dr. Jason LeBlanc

Directors, Virology and Immunology Section

DATE: December 9, 2013

RE: Changes in CMV viral load testing and interpretation cutoffs

Effective December 5th, 2013, CMV viral load testing will be performed using new methodology. Clinicians should be aware of the following changes for CMV viral load testing and interpretation cutoffs.

Since previous technology for CMV viral loads has been discontinued, we will be moving to quantitative real-time PCR on a fully automated instrument. This assay is calibrated against a World Health Organization (WHO) International Standard, which enables standardization of results and enhanced quality assurance. Therefore, CMV viral loads will be reported as CMV DNA International Units per milliliter (IU/ml), in contrast to copies/ml. The values for the new and old assays correlate very well. However, a recent publication suggests the cutoff for initiation of preemptive therapy for solid organ transplantation is slightly higher than the previous cutoff:

New cutoff values for result interpretation

High risk for developing CMV disease

- Solid organ transplant recipients: CMV viral load greater or equal to 2275 CMV DNA IU/ml suggests active CMV replication.
- Bone marrow and stem cell transplant recipients: CMV viral load greater or equal to 910 CMV DNA IU/ml suggests active CMV replication.

Low risk for CMV disease

- Solid organ transplant recipients: CMV DNA levels falling between 137 IU/ml and 2275 CMV DNA IU/ml; a repeat test in a week's time would be advisable.
- Bone marrow and stem cell transplant recipients: CMV DNA levels falling between 137 IU/ml and 910 CMV DNA IU/ml; a repeat test in a week's time would be advisable.

CMV disease unlikely

• Solid organ and bone marrow and stem cell transplant recipients: Lower limit of detection of the assay is 137 CMV DNA IU/ml.

If there are any questions regarding the results, they can be directed to Drs Todd Hatchette and Jason LeBlanc (473-6885 or 473-7698).