



Capital Health

MEMORANDUM

TO: Clinicians and Provincial Laboratories

FROM: Dr. Todd Hatchette / Dr. Jason LeBlanc
Directors Immunology / Virology Section

DATE: January 4, 2013

RE: Changes to Rubella and Hepatitis B antibody (anti-HBs) serology

Effective January 7, 2013, fourteen Microbiology serology tests will be performed using a new methodology. Clinicians should be aware of the following changes for Rubella and anti-HBs testing.

Changes in Rubella IgG grey zone:

During the validation of the Architect assay we found that the reproducibility of the Rubella IgG in the range of 8 to 15 IU/mL was low. Because of this variability we have instituted a grey zone of 8-15 IU/mL. The performance of this assay will be monitored after implementation and the grey zones may be modified in the future as new data is available. Please refer to the interpretation on the report.

Clinical Significance: Patients with an antibody level between 8 and 15 IU/mL may lack immunity and should be considered for vaccination. Serology should not be performed to document immunity post-vaccination.

We would like to remind clinicians that either:

- 1) Documentation of vaccination with a rubella-containing vaccine (e.g. MMR), OR
- 2) Positive rubella serology is considered adequate evidence of immunity (Canadian Immunization Guide, 2012).

Thus, women who are known to have received a rubella-containing vaccine or who have ever had positive rubella serology do not need serological testing as part of routine prenatal screening and are considered rubella-immune.

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Changes in anti-HBs grey zone:

Previously 10 mIU/mL was considered the cut-off for immunity and used to decide who would require intervention in the case of exposure to blood or bodily fluids. During the validation of the Architect, we found that the reproducibility of anti-HBs in the range of 8-12 was low. To ensure that we do not incorrectly identify a patient as immune when they may have titres below the protective range we have instituted a grey zone of 8-12 mIU/mL

Clinical Significance: Patients with an antibody titre of < 12 mIU/mL should be considered susceptible to Hepatitis B Virus (HBV) when exposed to blood or bodily fluids from a potentially infected individual and be triaged according to local protocols.

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

Sincerely,

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