

## Labstract – May 2018

# Hepatitis B Surface Antibody Serologic Testing Update - Changes to Screening test

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### Audience

Health Care Providers who order hepatitis B surface antibody testing.

### Overview

Effective May 7, 2018:

Public Health Ontario Laboratory (PHOL) is changing its testing and reporting of hepatitis B surface antibody (Anti-HBs). This change is being made as a result of restandardization to align the Abbott ARCHITECT Anti-HBs assay with the World Health Organization (WHO) 2<sup>nd</sup> International Reference Standard Preparation which has replaced the WHO 1<sup>st</sup> International Reference Standard Preparation. Restandardization does not adversely impact the clinical sensitivity or specificity performance of the assay. Results will be reported as an Anti-HBs concentration in mIU/mL with an overall interpretation of the patient's hepatitis B immune status.

### Background Information

The choice of hepatitis B virus (HBV) serologic tests should be based on patient history and clinical presentation for the appropriate diagnosis and management. For detailed information on serologic tests for HBV, please refer to the Public Health Agency of Canada Primary Care Management of Hepatitis B – Quick Reference (HBV-QR).

Anti-HBs assays are used to determine immunity to HBV, either following completion of a course of hepatitis B vaccine or following recovery from acute HBV infection. Testing with anti-HBs assays for post-immunization screening is not necessary after routine vaccination, but is recommended for those with ongoing risk of exposure to HBV (e.g., HBV-positive sexual partner, injection drug use). For a list of individuals recommended for post-vaccination serologic testing, please refer to the [Canadian Immunization Guide, Part – Active Vaccines, Hepatitis B Vaccine, Serologic Testing](#). In general, an anti-HBs level of  $\geq 10$  mIU/mL one to six months following completion of a recommended vaccine schedule is considered life-time immunity and no further testing or vaccination is required. However, there are exceptions for specific populations, such as immunocompromised persons and people with chronic renal disease. More detailed information on the appropriate post-immunization serologic testing and follow-up can be found in the Canadian Immunization Guide.

## Changes to the newly standardized Hepatitis B Surface Antibody [Anti-HBs] test and result reporting:

- Results will no longer be reported as either 'Reactive' or Non-reactive' for the detection of hepatitis B surface antibody.
- Results will be reported as an Anti-HBs concentration in mIU/mL. An Anti-HBs concentration  $\geq 10$  mIU/mL is regarded as being protective against hepatitis B virus infection.

**Note:** An overall interpretation of the patient's hepatitis B immune status will be provided as, either 'No evidence of immunity' when the Anti-HBs is  $< 10$  mIU/mL or 'Evidence of immunity' when the Anti-HBs is  $\geq 10$  mIU/mL.

## Specimen collection requirements

Human serum is the preferred specimen type for Anti-HBs testing. Whole blood should be allowed to clot. Use of serum separator tubes (SST) is acceptable. Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens and therefore are not recommended for specimen collection. Heat inactivated, haemolysed, icteric, lipemic or microbially contaminated sera are not recommended for testing.

[publichealthontario.ca/en/ServicesAndTools/LaboratoryServices/Pages/Hepatitis\\_B\\_Diagnostic\\_Serology.aspx](http://publichealthontario.ca/en/ServicesAndTools/LaboratoryServices/Pages/Hepatitis_B_Diagnostic_Serology.aspx)

## Testing Turnaround time (TAT)

TAT may be up to 3 days.

## References

1. Ferguson, M & Heath, A. 2008. Report of the WHO Collaborative Study to calibrate a candidate replacement for the First International Standard for Hepatitis B immunoglobulin. Pages 1-22.  
[apps.who.int/iris/bitstream/handle/10665/69968/WHO\\_BS\\_08.2084\\_eng.pdf;jsessionid=BFADD43A6BCA1B74CE9C4B61A5CF2B7F?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/69968/WHO_BS_08.2084_eng.pdf;jsessionid=BFADD43A6BCA1B74CE9C4B61A5CF2B7F?sequence=1)
2. Ferguson, M, Yu, M.W. & Heath, A. 2010. "Calibration of the second International Standard for hepatitis B immunoglobulin in an international collaborative study". *Vox Sanguinis, Intl Journal of Transfusion Medicine*, pages 1-8.
3. Schillie S, *et al.* 2013. "CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management". *Morbidity and Mortality Weekly Reports (MMWR)*. 62(RR10);1-19.
4. Mast EE, *et al.* 2006. "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States". *Morbidity and Mortality Weekly Reports (MMWR)*. 55(RR16);1-25.
5. Public Health Agency of Canada. Primary Care Management of Hepatitis B – Quick Reference (HBV-QR). February 26, 2014. Available at: [canada.ca/en/public-health/services/reports-publications/primary-care-management-hepatitis-b-quick-reference.html](http://canada.ca/en/public-health/services/reports-publications/primary-care-management-hepatitis-b-quick-reference.html)

6. Public Health Agency of Canada. Canadian Immunization Guide: Part 4 – Active Vaccines. June 29, 2017.  
Available at: [canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-7-hepatitis-b-vaccine.html#hbstitre](https://canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-7-hepatitis-b-vaccine.html#hbstitre)

## For further information

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at [CustomerServiceCentre@oahpp.ca](mailto:CustomerServiceCentre@oahpp.ca)
- For PHOL specimen collection information and previous Lababstracts, refer to [publichealthontario.ca/Labs](https://publichealthontario.ca/Labs)
- The current version of the PHOL General Test Requisition and other forms are available at [publichealthontario.ca/Requisitions](https://publichealthontario.ca/Requisitions)
- To subscribe to future Lababstracts, [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 PHOL Customer Service Centre.