

VITROS® ANTI-HBs Assay [Quantitative]

Fully automated. Random access. Now that's simple.

Hepatitis testing is simple with the VITROS Anti-HBs assay on the VITROS ECi/ECiQ Immunodiagnostic System. Ease of operation is just a start—in addition, you'll get advanced security, enhanced service levels, labor optimization, and cost containment all together in one unique system.

Advanced Security

- VITROS ECi/ECiQ Immunodiagnostic System using Intellicheck® Technology ensures quality result reporting

Cost Containment

- Broad analytical measurement range up to 1000 mIU/mL
 - Reduces dilution and repeats
- Extended stability
 - 28-day calibration stability
 - 56 day open on-board reagent stability

Labor Optimization

- Full automated random access, continuous sample load and unload
- Testing availability 24 hours a day/7 days a week
- Consolidation of hepatitis serology and core immunodiagnostic testing

Enhanced Service Levels

- Provide quantitative results to guide clinical management
- Results available in as little as 55 minutes
- Low sample volume of 80 μ L

Flexibility in Result Reporting

Both the quantitative result in mIU/mL and the result text are printed on the instrument patient report as well as transmitted to an LIS. Depending on the request from the physician, a result can either be reported using the result text for those requesting a qualitative indication of immune status or the quantitative result in mIU/mL with or without the result text. Further, your LIS can be configured to either capture the result flag, the quantitative result or both.

The VITROS Anti-HBs assay is intended for the quantitative *in vitro* determination of total antibody to hepatitis B surface antigen (anti-HBs) in human serum using the VITROS ECi/ECiQ Immunodiagnostic System using Intellicheck Technology.

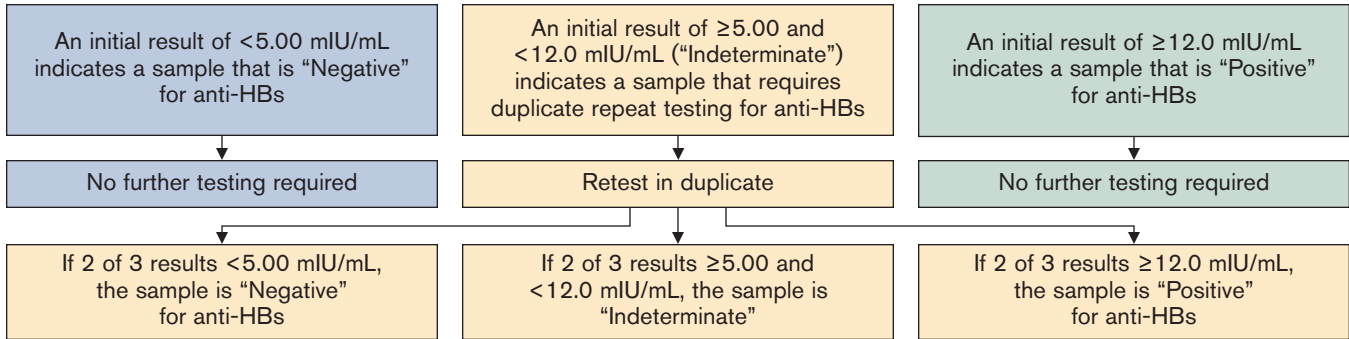
Assay results may be used as an aid in the determination of susceptibility to hepatitis B virus (HBV) infection for individuals prior to or following HBV vaccination, or where vaccination status is unknown. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. A reactive assay result will allow a differential diagnosis in individuals displaying signs and symptoms of hepatitis, in whom etiology is unknown.¹

WARNING: Assay performance characteristics have not been established when the VITROS Anti-HBs Quantitative assay is used in conjunction with other manufacturers' assays for specific HBV serological markers. Users are responsible for establishing their own performance characteristics.



Testing Algorithm

Final results should be manually interpreted using the algorithm below:



Clinical Interpretation Following Testing Algorithm

VITROS Anti-HBs Assay Result	Result Text	Clinical Interpretation of Immune Status
<5.00 mIU/mL	Negative	Patient is considered to be not immune to infection with HBV.
≥ 5.00 mIU/mL and <12.0 mIU/mL	Indeterminate	Unable to determine if anti-HBs is present at levels consistent with immunity. Patient's immune status should be further assessed by considering other clinical information or retesting another specimen drawn at a later time.
≥ 12.0 mIU/mL	Positive	Anti-HBs detected at >10 mIU/mL. Patient is considered to be immune to infection with HBV. It has not been determined what the clinical significance is for values ≥ 12 mIU/mL, other than the individual is considered to be immune to HBV infection.

Reportable Range

- 0-1,000 mIU/mL
- The VITROS ECi/ECiQ has the ability to perform automatic sample dilution up to 400 fold

Assay Limit of Detection

- As determined using NCCLS EP17,² the Limit of Detection (LoD) is 4.23 mIU/mL.
- Values between 0 mIU/mL and 4.23 mIU/mL should be interpreted as negative and not having detectable anti-HBs.
- Values between 4.23 mIU/mL and 5.0 mIU/mL indicates with 95% confidence that a sample contains anti-HBs, but not at levels consistent with protective immunity against HBV infection.

Calibration Accuracy

Calibration is traceable to the World Health Organization (WHO) First International Reference Preparation for Antibody to HBsAg (1977)³.

Ordering Information

VITROS Immunodiagnostic Products

Anti-HBs Reagent Pack	100 Tests	680 1925
Anti-HBs Calibrators	3 levels, liquid, 2mL each	680 1926
Anti-HBs Controls	3X (3 levels, 2mL each)	680 2093

References:

- VITROS Immunodiagnostic Products Anti-HBs Reagent Pack Instructions for Use. Refer to appropriate sections for additional information related to warnings and precautions about this device.
- NCCLS. Protocols for Determination of Limits of Detection and Limits of Quantitation; Proposed Guideline. NCCLS document EP17-P [ISBN 1-56238-000-0]. NCCLS, 940 West Valley Road, Suite 1400, Wayne Pennsylvania 19087-1898 USA, 2003.
- Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR*. 1991; 40 (RR-13): 8.

For more information contact your Ortho-Clinical Diagnostics representative or visit our website at www.orthoclinical.com.