

The VITROS® ANTI-HBc IgM Assay

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

Hepatitis testing is simple with the VITROS Anti-HBc IgM assay on the VITROS ECi 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

- The VITROS ECi Immunodiagnostic System using Intellicheck™ Technology ensures quality result reporting

Enhanced Service Levels

- First result in as little as 43 minutes
- Low sample volume of 10 µL
- Excellent precision
- Excellent discrimination of positive and negative samples around the cutoff

Labor Optimization

- Fully automated random access, continuous sample load and unload
- Testing availability 24 hours a day/7 days a week
- Consolidation of hepatitis serology with more than 30 multi-disease state assays

Cost Containment

- 28-day assay calibration stability
- 8 weeks—(56 days) on-board reagent stability



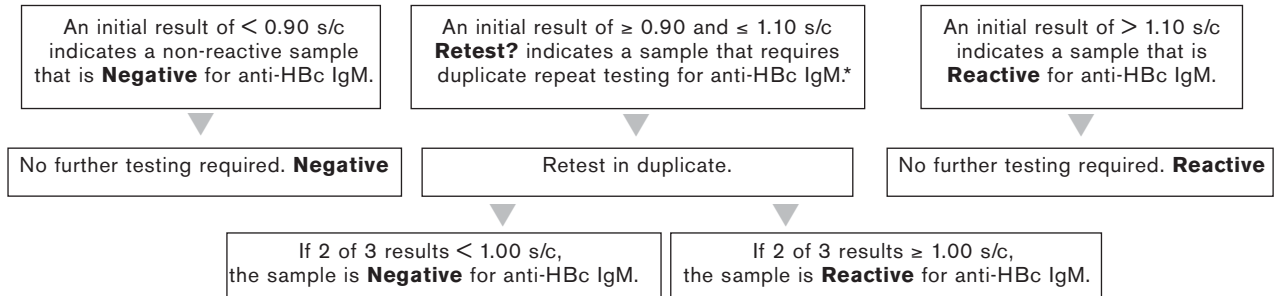
The VITROS Anti-HBc IgM Reagent Pack is intended for the *in vitro* qualitative detection of IgM antibody to hepatitis B core antigen (anti-HBc IgM) in human adult and pediatric serum and plasma (heparin, EDTA and citrate) and neonate serum using the VITROS ECi Immunodiagnostic System using Intellicheck Technology.

Assay results, in conjunction with other serological and clinical information, may be used for the laboratory diagnosis of individuals with acute or chronic hepatitis B.¹

¹ VITROS Immunodiagnostic products Anti-HBc IgM Reagent Pack Instructions For Use. Refer to appropriate sections for additional information related to intended use, warnings and limitations.

Efficient Testing Algorithm for VITROS® Anti-HBc IgM

Results are calculated as a signal, relative to the cutoff value (signal/cutoff, s/c).



- Excellent discrimination around the cutoff.
- Narrow retest zone reduces the number of repeat tests and improves turnaround time for reactive results.

*Neonate samples with results ≥ 0.90 and ≤ 1.10 s/c should not be retested in duplicate. Obtain a new sample and retest.

VITROS ANTI-HBc IgM ASSAY RESULT (s/c)	CONCLUSION FROM TESTING ALGORITHM	INTERPRETATION
< 0.90	Negative	Specimen is negative for anti-HBc IgM.
≥ 0.90 and ≤ 1.10	Retest in duplicate	Specimen is negative for anti-HBc IgM if 2 of 3 results are < 1.00. Specimen is presumed to be reactive for anti-HBc IgM if 2 of 3 results are ≥ 1.00 .
> 1.10	Reactive	Specimen is presumed to be reactive for anti-HBc IgM.

The VITROS ECi and the VITROS Anti-HBc IgM Assay: a productive combination.

The VITROS ECi Immunodiagnostic System is simple to use because it's fully automated and flexible. It provides truly continuous, STAT, random access capabilities for routine and specialty immunodiagnostic testing. The system also uses proprietary Enhanced Chemiluminescence detection technology to provide excellent assay performance. In addition, the VITROS ECi uses Intellicheck™ Technology—a technology designed to verify diagnostic checks throughout automated sample and assay processing—increasing the integrity and security of patient results. This helps to ensure greater confidence and productivity for your lab. Furthermore, the expanded test menu—which includes the Anti-HBc IgM assay—works with VITROS ECi, making it simple to achieve efficiency and productivity in the lab.

WARNING

- This assay has not been FDA cleared or approved for the screening of blood or plasma donors.

ORDERING INFORMATION

VITROS IMMUNODIAGNOSTIC PRODUCTS		CATALOG NO.
Anti-HBc IgM Reagent Pack	52 Tests	680 1425
Anti-HBc IgM Calibrator	1 vial, 2 mL	680 1426
Anti-HBc IgM Controls	1 box, 3 sets, 2 levels Recon., 0.5 mL D1 H ₂ O	680 1427

For more information, contact your Ortho-Clinical Diagnostics Representative or visit our Web site at www.orthoclinical.com.