

AccuVert™ HBV Seroconversion Panel PHM937 (0605-0039)

INTENDED USE

The AccuVert™ HBV Seroconversion Panel PHM937 (0605-0039) is a group of serial bleeds from an individual plasma donor during seroconversion. This panel is intended for use by diagnostics manufacturers and clinical laboratorians to evaluate their HBV test systems using well-characterized specimens, and to provide comprehensive data for comparative analysis. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product consists of a set of five undiluted plasma samples from a single plasma donor collected during a period of HBV seroconversion. All units were maintained frozen except for the interval of dispensing into vials. No preservatives were added.

Material Number: 0605-0039; 1 vial per member
5 members, 1.5 mL per vial

STORAGE

Panel members should be stored frozen at -20°C or colder for serology use and -70°C or colder for NAT use. LGC Clinical Diagnostics recommends that the panel members be divided into smaller aliquots, if appropriate, to avoid multiple freeze-thaw cycles. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

INTERPRETATION OF RESULTS

The Data Sheet for AccuVert HBV Seroconversion Panel PHM937 (0605-0039) is available at www.seracare.com. The Data Sheet lists results for panel members generated using commercially available screening, monitoring and confirmatory tests approved in the U.S. and/or the European Union. Tests were performed at LGC Clinical Diagnostics or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Information regarding specific test methods is available on the Data Sheet. Data Sheets are updated when new data are available.

LIMITATIONS

AccuVert HBV Seroconversion Panel PHM937 (0605-0039) is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC Clinical Diagnostics does not claim that others can duplicate test results exactly.

PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Follow Universal Precautions¹. Some panel members were found positive by tests for HBV markers including HBsAg. The units that make up this panel were tested and found negative for anti-HCV and anti-HIV 1/2. This does not ensure the absence of these or other human pathogens.

Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

These materials should be disposed of in a manner that will inactivate pathogenic agents.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact LGC Clinical Diagnostics at 508.244.6400.

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at CDx-Info@LGCGroup.com or by phone at 508.244.6400.