

AccuVert[™] HBV Seroconversion Panel PHM940 (0605-0059)

INTENDED USE

The AccuVert[™] HBV Seroconversion Panel PHM940 (0605-0059) is a group of serial bleeds from an individual plasma donor during HBV seroconversion. This panel is intended for use by diagnostics manufacturers and clinical laboratories 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

The product consists of a set of eight 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:

0605-0059,1 vial per member 8 members, 1.5 mL per vial

STORAGE

Panel members should be stored frozen at -70 °C or colder. LGC SeraCare 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 PHM940 (0605-0059) is available at <u>www.seracare.com</u>. 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. The tests that are listed were performed at LGC SeraCare 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 PHM940 (0605-0059) is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC SeraCare 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. 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 SeraCare at 508.244.6400.

The package insert for this panel can be found at <u>www.seracare.com</u>.

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