

A SERACARE PANEL PRODUCT

INTENDED USE

The HBV Seroconversion Panel, PHM936, 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

PHM936 consists of a set of 8 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.

Cat. No. PHM936-1.5 1 vial per member
8 members, 1.5 mL per vial

STORAGE

Panel members should be stored frozen at -10°C or colder. 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 HBV Seroconversion Panel PHM936 is available at www.seracarepanels.com. Select PHM936 from the list of panel data sheets. 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 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

PHM936 is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Follow Universal Precautions.¹ 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. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (supp.2) 1987.

For assistance, contact SeraCare Technical Support at 508.244.6400.

The Data Sheet for this panel in PDF form can be found at www.seracarepanels.com

The printed Data Sheet may be requested by email to info@seracare.com, or by phone to 508.244.6400

ASK ABOUT RELATED SERACARE PRODUCTS

- ACCURUN® independent quality controls
- SeraCon™ and other processed plasma products
- Global Patient Sample (GPS) Program – access to a vast and evolving inventory of single test patient samples