

HBsAg Low Titer AccuSet™ Performance Panel Modified PHA107(M) (0805-0304)

PACKAGE INSERT

INTENDED USE

The HBsAg Low Titer AccuSet™ Performance Panel Modified is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot HBsAg test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is a modified 18-member panel originating from HBsAg Low Titer Performance Panel PHA107-1.5. Panel members 12, 13, and 19 are no longer available. Panel members are naturally-occurring plasma samples from different individuals with test results from eleven commercially available HBsAg assays, including one quantitative method and one rapid test, an HBsAg neutralization method, and tests for several other HBV markers. No preservatives were added.

Cat. No. 0805-0304 1 vial per member
 18 members, 1.5 mL per vial

STORAGE

Panel members should be stored frozen at -20°C or colder. SeraCare Life Sciences recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. 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 the HBsAg Low Titer AccuSet™ Performance Panel is available at www.seracare.com. The Data Sheet lists results for panel members generated using commercially-available screening, monitoring, and

confirmatory test methods. Tests 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

The HBsAg Low Titer AccuSet™ Performance Panel 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

Follow Universal Precautions.¹ The units that make up this panel were tested and found negative for anti-HIV and anti-HCV. 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 SeraCare Technical Support at 508.244.6400.

The Package Insert and Data Sheet for this panel in PDF form can be found at www.seracare.com

A printed copy of the Data Sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400

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- ACCURUN® Quality Controls
- AccuType™ Viral Isolates
- SeraCon™ and Basematrix Processed Plasma

