

AccuSet[™] HBsAg Performance Panel 0805-0391

INTENDED USE

The AccuSet[™] HBsAg Performance Panel is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot HBV 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 25-member HBsAg performance panel. Panel members represent bleeds from multiple individuals positive for HBsAg and other HBV analytes. Panel members consist of undiluted, naturally-occurring plasma samples. Each sample represents a single collection event. One sample is included as a nonreactive sample and is negative for all HBV methods tested. No preservatives were added.

Material Number:

0805-0391, 1 vial per member 25 members, 1.5 mL per vial

STORAGE

Panel members should be stored frozen at -20 °C or colder. SeraCare 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 AccuSet[™] HBsAg Performance Panel 0805-0391 is available at <u>www.seracare.com</u>. 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

Accuset[™] HBsAg Performance Panel 0805-0391 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 Precautions¹. 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. Panel members were found positive for HBsAg and other HBV related analytes.

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

 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 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>info@seracare.com</u> or by phone at 508.244.6400.