

Hepatitis B Surface Antigen (HBsAg) AccuSpan™

Sensitivity Panel

2410-0161

INTENDED USE

The Hepatitis B Surface Antigen (HBsAg) AccuSpan™ Sensitivity Panel, 2410-0161, is intended to be used in evaluating the low end sensitivity and linearity of HBsAg assays. It is a 15 member panel made from two dilution series of HBsAg subtypes ad and ay. This panel is designed to enable users to challenge their HBsAg test systems.

For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The HBsAg AccuSpan Sensitivity Panel consists of two sets of dilution series; one of HBsAg subtype ad and one of HBsAg subtype ay. Each dilution series consists of seven members representing serial two-fold dilutions of positive serum with established reactivity for each HBsAg subtype diluted in negative diluent. The panel also includes a negative member prepared from the negative diluent. The diluent was prepared from pooled normal human serum non-reactive for HBsAg that was filtered through a 0.2 micron filter. Each member contains a preservative (0.1% ProClin 300).

Item No. 2410-0161	1 vial per member
	15 members, 1.5 mL per vial

STORAGE

This panel is stable until the labeled expiration date if stored at -20°C or colder. Once thawed and opened, vials should not be reused. Alterations in physical appearance may indicate instability or deterioration. Solutions that are visibly turbid should be discarded.

INSTRUCTIONS FOR USE

Each panel member should be tested following the same procedure used for unknown samples according to the test manufacturer's instructions. Thaw the panel at room temperature and mix by gentle inversion before using.

INTERPRETATION OF RESULTS

The Data Sheet for the HBsAg AccuSpan Sensitivity Panel is available at www.seracare.com. Results were generated using FDA cleared and CE marked HBsAg quantitative and qualitative assays. Tests were performed at a recognized reference laboratory by individuals who routinely use these procedures.

LIMITATIONS

The HBsAg AccuSpan Sensitivity 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

These materials have not been treated and should be considered biohazardous. Use the CDC recommended Universal Precautions for handling this product¹. 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 at 508.244.6400.

The package insert and data sheet 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 info@seracare.com or by phone at 508.244.6400