

AccuSpan™ HBV DNA Linearity Panel 2410-0162

INTENDED USE

The AccuSpan™ HBV DNA Linearity Panel, 2410-0162, is intended to be used in evaluating the dynamic range of quantitative HBV DNA assays. It is a nine member panel made from serial dilutions of HBV DNA positive plasma with established reactivity for Hepatitis B (HBV) DNA. This panel can be used for monitoring HBV DNA recovery at defined intervals, identifying consistency over a linear range, verifying lot changes, performing linearity studies, operator training, or whenever there are indications of possible assay deterioration.

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

PRODUCT DESCRIPTION

The AccuSpan HBV DNA Linearity panel consists of eight positive members representing serial log dilutions of HBV DNA positive plasma in HBV DNA negative diluent and one negative member prepared from the diluent. The eight positive members are each prepared from the preceding member by diluting HBV DNA positive plasma with HBV DNA negative diluent in serial ten-fold dilutions beginning at member 1, the highest positive member, ending with member 8, the lowest positive member. The diluent was prepared from normal human plasma that was filtered through a 0.2 micron filter. Each member contains a preservative (0.09% sodium azide).

Material Number: 2410-0162, 1 vial per member
9 members, 1.2 mL per vial

STORAGE

This panel is stable until the labeled expiration date if stored at -70°C or colder. Alternatively, panels may be stored for up to 6 months at -20°C as long as the panels are used before the labeled expiration date. Label panels with date that -20°C storage began. Once thawed and opened, vials can be used up to three times and must be used within 10 days after opening. Store vials at 2-8°C between uses. 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 AccuSpan HBV DNA Linearity Panel is available at www.seracare.com. Results were generated using FDA cleared HBV DNA quantitative assays standardized to the World Health Organization (WHO) International Standard. Tests were performed at recognized reference laboratories by individuals who routinely use these procedures.

LIMITATIONS

The AccuSpan HBV DNA Linearity Panel is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC 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.

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
www.seracare.com.

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