

AccuSpan™ BKV Linearity Panel 2410-0344

INTENDED USE

The AccuSpan BKV Linearity Panel 2410-0344 is intended to be used in evaluating the dynamic range of quantitative BKV DNA assays. This panel can be used for monitoring BKV DNA recovery at defined intervals, identifying consistency over a linear range, verifying lot changes, performing linearity studies, operator training, or for troubleshooting signs of assay deterioration. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The AccuSpan BKV Linearity Panel consists of six positive members representing serial log dilutions of cultured BK virus in BKV negative diluent and one negative member prepared from the diluent. The six positive members are each prepared from the preceding member by diluting cultured BKV DNA with BKV DNA negative diluent in serial ten-fold dilutions beginning at member 1, the highest positive, and going to member 6, the lowest positive. 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: 2410-0344, 1 vial per member
7 members, 1.4 mL per vial

STORAGE

This panel is stable until the labeled expiration date if stored at -70°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. LGC CDx recommends that each vial is mixed by vortexing prior to use.

INTERPRETATION OF RESULTS

The Data Sheet for AccuSpan BKV Linearity Panel 2410-0344 is available at www.seracare.com. Results were generated using FDA cleared BKV 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 BKV Linearity Panel 2410-0344 is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC CDx 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.

Table 1: Target Concentrations

Panel Member	Target Concentration (IU/mL)
Member 1	20,000,000
Member 2	2,000,000
Member 3	200,000
Member 4	20,000
Member 5	2,000
Member 6	200
Member 7	Target Not Detected

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.