

AccuSpan™ HIV-1 RNA Linearity Panel 2410-0221

INTENDED USE

The AccuSpan[™] HIV-1 RNA Linearity Panel, 2410-0221, is intended to be used in evaluating the dynamic range of quantitative HIV-1 RNA assays. It is a ten member panel made from serial dilutions of a cultured virus with established reactivity for HIV-1 (Human Immunodeficiency Virus 1, 8E5). This panel can be used for monitoring HIV-1 RNA 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 HIV-1 RNA Linearity Panel consists of eight positive members representing serial log dilutions of cultured HIV-1 virus in HIV-1 RNA negative diluent, one negative member prepared from the diluent, and one member of diluent to perform additional dilutions as desired. The eight positive members are each prepared from the preceding member by diluting cultured HIV-1 virus with HIV-1 RNA negative diluent in serial ten-fold dilutions beginning at member 1, the highest positive member, and going to member 8, 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:

2410-0221 1 vial per member 10 members, 1.2 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 and mix by gentle inversion before using.

INTERPRETATION OF RESULTS

The Data Sheet for the AccuSpan HIV-1 RNA Linearity Panel (2410-0221) is available at <u>www.seracare.com</u>. Results were generated using FDA cleared HIV-1 RNA quantitative assays standardized to the 3rd World Health Organization (WHO) International Standard. Tests were performed at recognized reference laboratories by individuals who routinely use these procedures.

LIMITATIONS

AccuSpan HIV-1 RNA Linearity Panel (2410-0221) 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 <u>CDx-Info@LGCGroup.com</u> or by phone at 508.244.6400.