AccuSpan™ HCV RNA Linearity Panel

PHW805 (2410-0166)

INTENDED USE

The AccuSpan™ HCV RNA Linearity Panel PHW805 (2410-0166) is intended to be used in evaluating the dynamic range of quantitative HCV RNA assays. It is an eight member panel made from serial dilutions of high titer, naturally-occurring HCV RNA positive plasma. This panel can be used for monitoring HCV RNA recovery at defined intervals, identifying consistency over a linear range, verifying lot changes, performing linearity studies, or whenever there are indications of possible assay deterioration.

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

PRODUCT DESCRIPTION

This product consists of seven positive members representing serial log dilutions of naturally occurring HCV in HCV RNA negative diluent and one negative member prepared from the diluent. The seven positive members are each prepared from the preceding member by diluting HCV RNA positive plasma with HCV RNA negative diluent in serial ten-fold dilutions beginning at member 1, the highest positive, and ending with member 7, the lowest positive. The HCV genotype used in this panel has been identified as type 1. The diluent was prepared from normal human plasma negative for HCV RNA and was filtered through a 0.2 micron filter. Each member contains a preservative (0.09% sodium azide).

Material Number:	2410-0166, 1 vial per member 8 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 AccuSpan HCV RNA Linearity Panel PHW805 (2410-0166) is available at www.seracare.com. Results were generated using FDA cleared HCV RNA 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

AccuSpan HCV RNA Linearity Panel PHW805 (2410-0166) is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC Clinical Diagnostics 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 product[1].

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 Clinical Diagnostics 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.