# PACKAGE INSERT

## **INTENDED USE**

The HCV Low Titer AccuSet<sup>™</sup> Performance Panel is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot HCV test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

## **PRODUCT DESCRIPTION**

This product is an 11-member panel consisting of undiluted, naturally occurring plasma samples. Panel members represent bleeds from multiple individuals positive for HCV with low titer reactivity for anti-HCV. Each sample represents a single collection event. One sample is included as a non-reactive sample and is negative for all HCV methods tested. No preservatives were added.

Cat. No. 0810-0192

1 vial per member 11 members, 1,2 mL per vial

#### STORAGE

Panel members should be stored frozen at -20°C or colder. SeraCare Life Sciences recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

## **INTERPRETATION OF RESULTS**

The Data Sheet for the HCV Low Titer AccuSet<sup>™</sup> Performance Panel is available at <u>www.seracare.com</u>. The Data Sheet lists results for panel members generated using commercially-available screening, monitoring, and confirmatory test methods. Tests were performed at

The Package Insert and Data Sheet for this panel in PDF form can be found at <u>www.seracare.com</u>

A printed copy of the Data Sheet may be requested by email at <u>info@seracare.com</u>, or by phone at 508.244.6400

SeraCare or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Information regarding specific test methods is available on the Data Sheet. Data Sheets are updated when new data are available.

#### LIMITATIONS

The HCV Low Titer AccuSet<sup>™</sup> Performance 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

Follow Universal Precautions.<sup>1</sup> The units that make up this panel were tested and found negative for anti-HIV 1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

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 Technical Support at 508.244.6400.

## ASK ABOUT RELATED SERACARE PRODUCTS

- AccuType<sup>™</sup> Viral Isolates
- ACCURUN<sup>®</sup> Quality Controls
- Disease State Biological Materials
- AccuVert<sup>™</sup> Seroconversion Panels



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