

PACKAGE INSERT

INTENDED USE

The HIV-1 RNA EDTA AccuSet™ Performance Panel is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot HIV-1 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 a 12-member panel consisting of undiluted, naturally occurring plasma samples. Panel members represent bleeds collected in K2 EDTA from multiple individuals positive for HIV. Each sample represents a single collection event. Panel members demonstrate reactivity ranging from negative to strongly positive for HIV-1 RNA. No preservatives were added.

Cat. No. 0800-0315 1 vial per member
 12 members, 1.2 mL per vial

STORAGE

Panel members should be stored frozen at -70°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 HIV-1 RNA EDTA AccuSet™ Performance Panel is available at www.seracare.com. The Data Sheet lists results for panel members generated using commercially-available screening, monitoring, and confirmatory test methods. Tests were performed at

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 HIV-1 RNA EDTA AccuSet™ 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.¹ The units that make up this panel were tested for HIV-1 RNA and most panel members were found positive. 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.

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

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

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- ACCURUN® Quality Controls
- AccuType™ Viral Isolates
- SeraCon™ and Basematrix Processed Plasma

