

AccuVert[™] HIV-1 Seroconversion Panel PRB962 (0600-0244)

INTENDED USE

The AccuVert[™] HIV-1 Seroconversion Panel PRB962 (0600-0244) is a group of serial bleeds from an individual plasma donor during HIV seroconversion. This panel is intended for use by diagnostic manufacturers and clinical laboratories to evaluate their HIV-1 test systems using well characterized specimens, and to provide comprehensive data for comparative analysis. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is a 6-member HIV seroconversion panel. Panel members represent serial bleeds from a single donor during the development and progression of a HIV infection. Panel members consist of undiluted, naturally occurring plasma samples. Each sample represents a single collection event. No preservatives were added.

Material Number:

0600-0244, 1 vial per member 6 members, 1.0 mL per vial

STORAGE

Panel members should be stored frozen at -20°C or colder. Storage at -70°C is recommended to preserve HIV RNA levels. SeraCare Life Sciences recommends that the panel members be divided into smaller aliquots for ease in repeated testing and to avoid multiple freeze-thaw cycles. 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 AccuVert HIV-1 Seroconversion Panel PRB962 (0600-0244) 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 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

AccuVert HIV-1 Seroconversion Panel PRB962 (0600-0244) 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

These materials have not been treated and should be considered biohazardous. Some panel members were found positive by tests for HIV markers including HIV RNA and HIV antigen. Follow Universal Precautions¹. The units that make up this panel were tested and found negative for HBsAg and anti-HCV. 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

 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 at 508.244.6400.

The package insert for this panel can be found at <u>www.seracare.com</u>.

A printed copy of the package insert or data sheet may be requested by email at <u>info@seracare.com</u> or by phone at 508.244.6400.