Anti-HIV-1 Low Titer Performance Panel Modified

PRB109(M) (0800-0301)

A SERACARE PANEL PRODUCT

INTENDED USE

The Anti-HIV-1 Low Titer Performance Panel Modified PRB109(M) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot HIV 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 modified 16-member panel originating from Anti-HIV-1 Low Titer Performance Panel PRB109-1.0. Panel members 5, 6, 9, and 18 from the original 20-member panel are no longer available. Panel members are undiluted, naturally occurring plasma samples collected from blood donors in the United States. Samples were selected to provide anti-HIV-1 reactivity near the sensitivity limits of anti-HIV screening test methods. Criteria for inclusion in this panel included on-scale sample signal to cut-off ratio (s/co) for at least one FDA-licensed anti-HIV screening test, and one of the following: a minimally positive, indeterminate, or negative Western Blot, and detectable HIV-1 RNA. One sample is included as a non-reactive sample and is negative by all methods tested. No preservatives were added.

Cat. No. 0800-0301	1 vial per member 16 members, 1.0 mL per vial

STORAGE

Panel members should be stored 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.

The 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

INTERPRETATION OF RESULTS

The Data Sheet for the Anti-HIV-1 Low Titer Performance Panel Modified 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 Anti-HIV-1 Low Titer Performance Panel Modified 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 and found negative for HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens. Most panel members were found positive by tests for anti-HIV-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 SeraCare Technical Support at 508.244.6400.

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