

*A SERACARE PANEL PRODUCT*

**INTENDED USE**

The HIV-1 Seroconversion Panel PRB962 is a group of serial bleeds from an individual plasma donor during seroconversion. This Panel is intended for use by diagnostics manufacturers and clinical laboratorians 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**

PRB962 consists of a set of six undiluted plasma samples from a single plasma donor collected during a period of HIV-1 seroconversion. All units were maintained in a frozen state, except for the interval of dispensing into vials. No preservatives were added.

Cat. No. PRB962-1.0 1 vial per member  
6 members, 1.0 mL per vial

**STORAGE**

Panel members should be stored frozen at -65°C to -80°C to preserve HIV-1 RNA. HIV antibody and antigen will be preserved at -10°C or colder. SeraCare recommends that the panel members be divided into smaller aliquots, if appropriate, 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 HIV-1 Seroconversion Panel PRB962 is available at [www.seracarepanels.com](http://www.seracarepanels.com). Select PRB962 from the list of panel data sheets. The Data Sheet lists results for panel members generated using

commercially available screening, monitoring and confirmatory tests approved in the U.S. and/or the European Union. The tests that are listed 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**

PRB962 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. Follow Universal Precautions.<sup>1</sup> Some panel members were found positive by tests for HIV markers including HIV-1 RNA and HIV-1 antigen. The units that make up this panel were found negative for anti-HCV 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. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (supp.2) 1987.

**For assistance, contact SeraCare Technical Support at 508.244.6400.**

*ASK ABOUT RELATED SERACARE PRODUCTS*

- ACCURUN® independent quality controls
- SeraCon™ and other processed plasma products
- Global Patient Sample (GPS) Program – access to a vast and evolving inventory of single test patient samples

The Data Sheet for this panel in PDF form can be found at [www.seracarepanels.com](http://www.seracarepanels.com)

The printed Data Sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

## OVERVIEW

This Data sheet contains test results specific for HIV-1 Seroconversion Panel PRB962.

PRB962 panel members are undiluted, unpreserved aliquots from plasma units collected in 2000 from a single donor, whose HIV RNA level increased from 760 to 12,000,000 copies/ml in ten days.

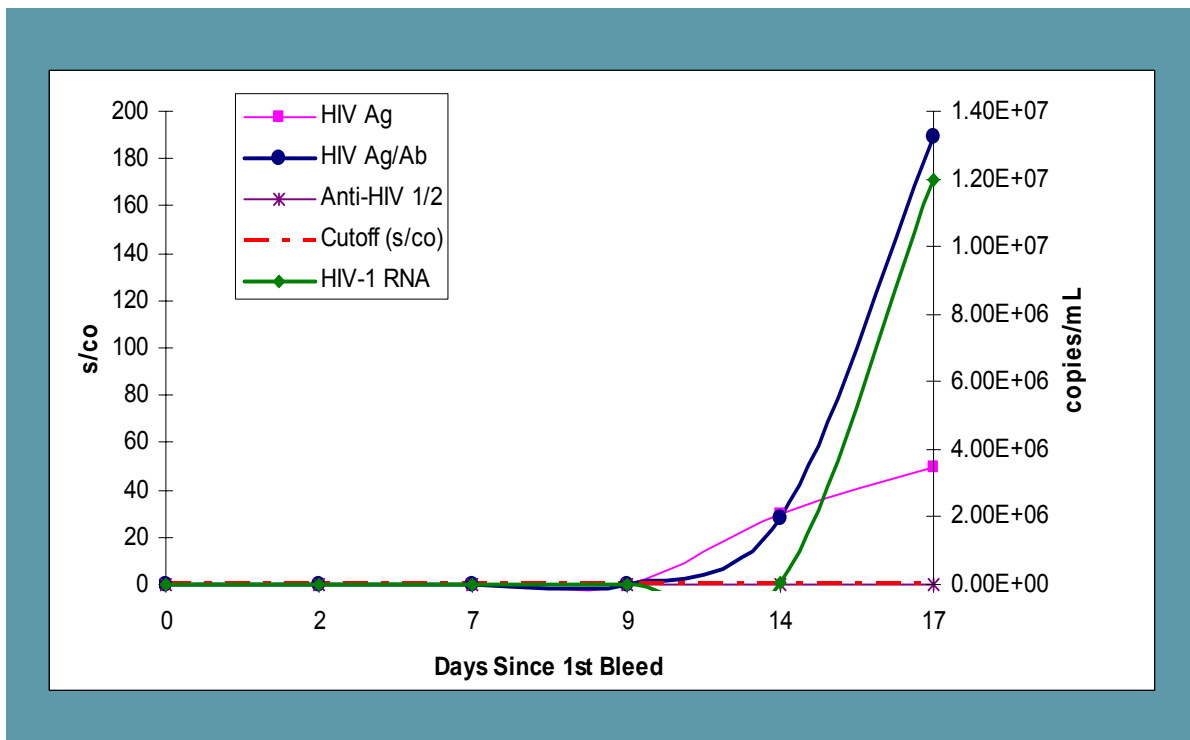
**CAUTION:** Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for anti-HIV; all were found negative for HBsAg and anti-HCV.

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Not for use in diagnostic procedures.

Data are offered for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated exactly.

## EVOLUTION OF HIV MARKERS IN EARLY INFECTION



*This graph demonstrates the evolution of early HIV infection, illustrated with test results over time for different analytes or analyte combinations.*

**HIV RNA (copies/mL)**

| Panel Member  | Bleed Date | Days Since 1 <sup>st</sup> Bleed | Fiebig Stage <sup>1</sup> | Roche Ultra Sensitive HIV-1 RNA | Roche Standard HIV-1 RNA |
|---------------|------------|----------------------------------|---------------------------|---------------------------------|--------------------------|
| PRB962-01     | 21-Mar-00  | 0                                | NA                        | <50                             | NT                       |
| PRB962-02     | 23-Mar-00  | 2                                | NA                        | <50                             | NT                       |
| PRB962-03     | 28-Mar-00  | 7                                | I                         | NT                              | 7.6 x 10 <sup>2</sup>    |
| PRB962-04     | 30-Mar-00  | 9                                | I                         | NT                              | 7.7 x 10 <sup>3</sup>    |
| PRB962-05     | 4-Apr-00   | 14                               | II                        | NT                              | 7.0 x 10 <sup>5</sup>    |
| PRB962-06     | 7-Apr-00   | 17                               | II                        | NT                              | 1.2 x 10 <sup>7</sup>    |
| Test Date     |            |                                  |                           | 3-May-07                        | 20-Apr-07                |
| Test Site     |            |                                  |                           | SC                              | SC                       |
| Kit Part Code |            |                                  |                           | 21118560018                     | 21118560018              |
| Kit Lot No.   |            |                                  |                           | H14002                          | H04637                   |
| Kit Exp. Date |            |                                  |                           | 29-Feb-08                       | 31-Aug-07                |

1. Fiebig stages are categories that define phases of early HIV infection. See Fiebig EW, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS 2003, 17:1871-9, and Lee HY, et al. Modeling sequence evolution in acute HIV-1 infection. JTB 2009, 261:341-360.

**HIV Antigen (s/co)<sup>2</sup>**

| Panel Member  | Bleed Date | Days Since 1 <sup>st</sup> Bleed | Coulter ELISA HIV-1 Ag | Perkin Elmer ELISA HIV-1 Ag | Roche Elecsys HIV-1 Ag | Zeptometrix ELISA HIV-1 Ag |
|---------------|------------|----------------------------------|------------------------|-----------------------------|------------------------|----------------------------|
| PRB962-01     | 21-Mar-00  | 0                                | 0.3                    | 0.3                         | 0.1                    | 0.1                        |
| PRB962-02     | 23-Mar-00  | 2                                | 0.2                    | 0.2                         | 0.2                    | 0.2                        |
| PRB962-03     | 28-Mar-00  | 7                                | 0.2                    | 0.2                         | 0.2                    | 0.2                        |
| PRB962-04     | 30-Mar-00  | 9                                | 0.6                    | 0.3                         | 0.3                    | 0.3                        |
| PRB962-05     | 4-Apr-00   | 14                               | >40.0                  | 29.6                        | 22.6                   | 9.6                        |
| PRB962-06     | 7-Apr-00   | 17                               | >40.0                  | >49.2                       | 154.6                  | 23.7                       |
| Test Date     |            |                                  | 4-Apr-07               | 24-May-07                   | 23-May-07              | 22-Mar-07                  |
| Test Site     |            |                                  | SC                     | SC                          | RL                     | SC                         |
| Kit Part Code |            |                                  | 626391                 | NEK 050A                    | NA                     | 801111                     |
| Kit Lot No.   |            |                                  | 2066F514               | 394387                      | 176936-01              | 303199                     |
| Kit Exp. Date |            |                                  | 18-Apr-07              | 16-Nov-07                   | 31-Aug-07              | 18-Jan-08                  |

2. Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

NT= Not tested, NA = Not available; Neg = Negative  
SC = SeraCare; RL = Reference Lab

**HIV Antigen/Antibody (s/co)<sup>1</sup>**

| Panel Member  | Bleed Date | Days Since 1 <sup>st</sup> Bleed | Abbott ARCHITECT Combo HIV Ag/Ab | Abbott AxSYM Combo HIV Ag/Ab | Abbott Murex Combination HIV Ag/Ab | Abbott PRISM Combo HIV Ag/Ab | Dade Behring Enzygnost Integral II HIV Ag/Ab | Roche Elecsys Combi HIV Ag/Ab |
|---------------|------------|----------------------------------|----------------------------------|------------------------------|------------------------------------|------------------------------|--|-------------------------------|
| PRB962-01     | 21-Mar-00  | 0                                | 0.2                              | 0.4                          | 0.3                                | 0.1                          | 0.1  | 0.2                           |
| PRB962-02     | 23-Mar-00  | 2                                | 0.2                              | 0.4                          | 0.3                                | 0.1                          | 0.1  | 0.3                           |
| PRB962-03     | 28-Mar-00  | 7                                | 0.2                              | 0.4                          | 0.3                                | 0.1                          | 0.1  | 0.3                           |
| PRB962-04     | 30-Mar-00  | 9                                | 0.3                              | 0.5                          | 0.3                                | 0.2                          | 0.2  | 0.3                           |
| PRB962-05     | 4-Apr-00   | 14                               | 28.4                             | 15.1                         | 9.9                                | 11.3                         | 11.9   | 3.7                           |
| PRB962-06     | 7-Apr-00   | 17                               | 189.6                            | 46.9                         | >max                               | 70.8                         | 11.7   | 22.8                          |
| Test Date     |            |                                  | 10-May-07                        | 14-May-07                    | 23-May-07                          | 16-May-07                    | 23-May-07                                    | 23-May-07                     |
| Test Site     |            |                                  | RL                               | RL                           | RL                                 | RL                           | RL   | RL                            |
| Kit Part Code |            |                                  | 4J27-30                          | 2G83-20                      | GE41                               | 7G46-48                      | OQTO 11                                      | 04860446                      |
| Kit Lot No.   |            |                                  | 52051HN00                        | 52433LU00                    | L000010                            | 52387HN00                    | 36815  | 178860-01                     |
| Kit Exp. Date |            |                                  | 2-Jan-08                         | 12-Oct-07                    | 30-Nov-07                          | 23-Oct-07                    | 6-Jun-08                                     | 30-Nov-07                     |

**HIV Antibody (s/co)<sup>1</sup>**

| Panel Member  | Bleed Date | Days Since 1 <sup>st</sup> Bleed | Abbott AxSYM HIV 1/2 gO | Abbott EIA HIV 1/2 | Abbott PRISM HIV O plus HIV 1/2 gO | Abbott Murex HIV 1.2.O HIV 1/2 gO | Siemens HIV 1/O/2 Enhanced Advia Centaur |
|---------------|------------|----------------------------------|-------------------------|--------------------|------------------------------------|-----------------------------------|--|
| PRB962-01     | 21-Mar-00  | 0                                | 0.4                     | 0.1                | 0.3                                | 0.2                               | 0.2                                      |
| PRB962-02     | 23-Mar-00  | 2                                | 0.4                     | 0.1                | 0.3                                | 0.2                               | 0.1                                      |
| PRB962-03     | 28-Mar-00  | 7                                | 0.4                     | 0.1                | 0.3                                | 0.2                               | 0.1                                      |
| PRB962-04     | 30-Mar-00  | 9                                | 0.4                     | 0.1                | 0.3                                | 0.2                               | 0.1                                      |
| PRB962-05     | 4-Apr-00   | 14                               | 0.4                     | 0.1                | 0.3                                | 0.2                               | 0.1                                      |
| PRB962-06     | 7-Apr-00   | 17                               | 0.5                     | 0.1                | 0.3                                | 0.4                               | 0.2                                      |
| Test Date     |            |                                  | 24-May-07               | 18-May-07          | 24-May-07                          | 24-May-07                         | 25-May-07                                |
| Test Site     |            |                                  | RL                      | SC                 | RL                                 | RL                                | RL                                       |
| Kit Part Code |            |                                  | 3D41-20                 | 3A77               | 7G46-48                            | GE94                              | 01463908                                 |
| Kit Lot No.   |            |                                  | 50220LU00               | 50178M200          | 52543HN00                          | L000710                           | 96445025                                 |
| Kit Exp. Date |            |                                  | 17-Oct-07               | 10-Jul-07          | 8-Jan-08                           | 28-Feb-08                         | 19-Mar-08                                |

1. Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

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SC = SeraCare; RL = Reference Lab

**Anti-HIV Confirmatory and Rapid Tests**

| Panel Member  | Bleed Date | Days Since 1 <sup>st</sup> Bleed | Maxim <sup>1</sup> Western Blot HIV-1 Band Pattern | Maxim <sup>1</sup> Western Blot HIV-1 Result | OraSure Rapid HIV-1 |
|---------------|------------|----------------------------------|--|--|---------------------|
| PRB962-01     | 21-Mar-00  | 0                                | No Bands   | Neg  | Neg                 |
| PRB962-02     | 23-Mar-00  | 2                                | No Bands   | Neg  | Neg                 |
| PRB962-03     | 28-Mar-00  | 7                                | No Bands   | Neg  | Neg                 |
| PRB962-04     | 30-Mar-00  | 9                                | No Bands   | Neg  | Neg                 |
| PRB962-05     | 4-Apr-00   | 14                               | No Bands   | Neg  | Neg                 |
| PRB962-06     | 7-Apr-00   | 17                               | No Bands   | Neg  | Neg                 |
| Test Date     |            |                                  | 11-Jun-07  | 18-May-07                                    |                     |
| Test Site     |            |                                  | SC   | SC   |                     |
| Kit Part Code |            |                                  | 98002  | 6341   |                     |
| Kit Lot No.   |            |                                  | F7242-027  | 6601644                                      |                     |
| Kit Exp. Date |            |                                  | 30-Aug-07  | 30-Sep-07                                    |                     |

1. Formerly Calypte – Cambridge Biotech Western Blot

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