

OVERVIEW

PRB956 is a five member HIV Seroconversion Panel collected from a single donor over a period of 50 days in which the donor seroconverted. This collection took place in 1997. Member 2 is a low titer HIV RNA sample. Fiebig stages I, II, and III are represented when the most sensitive antibody tests are used. Member 5 is a challenging antibody sample.

Panel Members are undiluted aliquots from plasma units. No preservatives were added.

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.

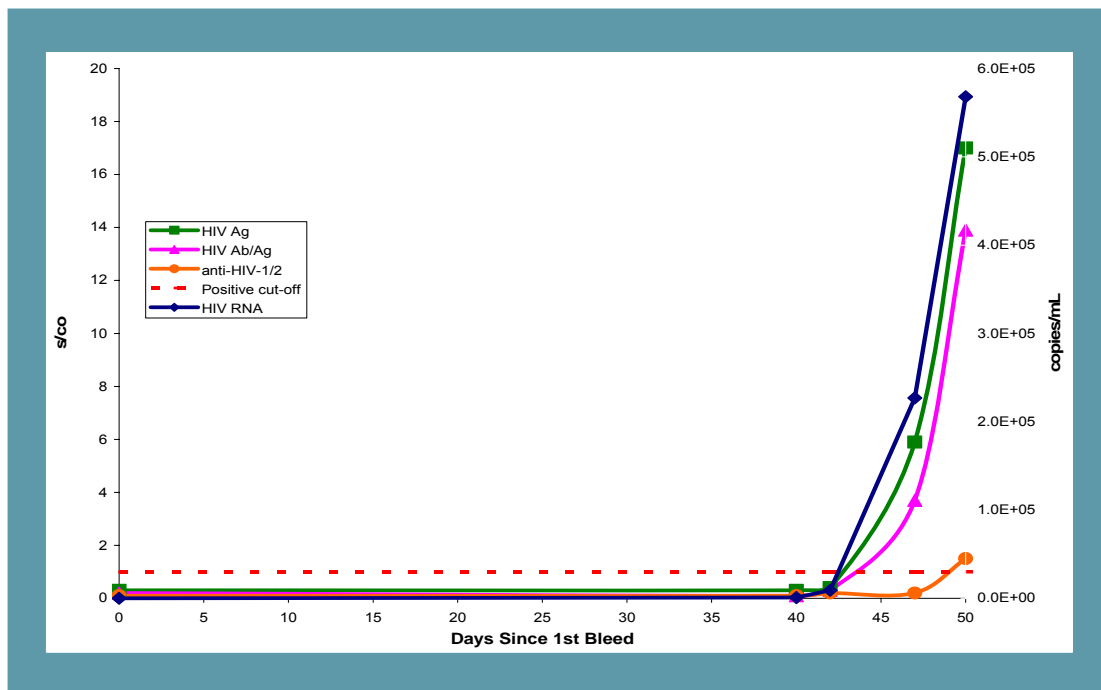
For Research Use Only. Not for use in diagnostic procedures.

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

PRB956 has been tested with current test methods. This Data Sheet consists of the previously generated data along with the newly generated data. The new data are presented in bold font.

For assistance, contact SeraCare Technical Support at 508.244.6400

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.

DATA SHEET

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HIV RNA (copies/mL)

| Panel Member | Bleed Date | Days Since 1 st Bleed | Fiebig Stage ¹ | Abbott HIV RNA m2000 | Chiron Quantiplex HIV RNA 2.0 bDNA | Organon Teknika NucliSens HIV-1 QT |
|---------------|------------|----------------------------------|---------------------------|-----------------------|------------------------------------|------------------------------------|
| PRB956-01 | 03-Jul-97 | 0 | NA | BLD | BLD | BLD |
| PRB956-02 | 12-Aug-97 | 40 | I | 7.1 x 10 ² | 1.0 x 10 ² | 3.0 x 10 ² |
| PRB956-03 | 14-Aug-97 | 42 | I | 7.2 x 10 ³ | 4.0 x 10 ³ | 7.0 x 10 ³ |
| PRB956-04 | 19-Aug-07 | 47 | II | 1.6 x 10 ⁵ | 1.0 x 10 ⁵ | 4.0 x 10 ⁵ |
| PRB956-05 | 22-Aug-97 | 50 | III | 3.0 x 10 ⁵ | 3.0 x 10 ⁵ | 8.0 x 10 ⁵ |
| Test Date | | | | 14Jan11 | 03Nov99 | 07Jan00 |
| Test Site | | | | RL | SC | SC |
| Kit Part Code | | | | 6L18 | 116147 | 84043 |
| Kit Lot No. | | | | 426021 | Z015 | 99092304 |
| Kit Exp Date | | | | 24Sep11 | 16Jan00 | 30Sep00 |

HIV RNA (copies/mL)

| Panel Member | Bleed Date | Days Since 1 st Bleed | Fiebig Stage ¹ | Roche Amplicor HIV-1 Monitor | Roche HIV RNA CAP/CTM v1.0 | Siemens HIV RNA bDNA |
|---------------|------------|----------------------------------|---------------------------|------------------------------|----------------------------|-----------------------|
| PRB956-01 | 03-Jul-97 | 0 | NA | BLD | BLD | BLD |
| PRB956-02 | 12-Aug-97 | 40 | I | 8.0 x 10 ² | 8.3 x 10 ² | 8.4 x 10 ¹ |
| PRB956-03 | 14-Aug-97 | 42 | I | 1.0 x 10 ⁴ | 9.1 x 10 ³ | 3.2 x 10 ³ |
| PRB956-04 | 19-Aug-07 | 47 | II | 6.0 x 10 ⁵ | 2.3 x 10 ⁵ | 6.3 x 10 ⁴ |
| PRB956-05 | 22-Aug-97 | 50 | III | 8.0 x 10 ⁵ | 5.7 x 10 ⁵ | 6.0 x 10 ⁴ |
| Test Date | | | | 27Feb99 | 19Jan11 | 14Jan11 |
| Test Site | | | | SC | RL | RL |
| Kit Part Code | | | | 83088 | 03542998 190 | 127418A/B |
| Kit Lot No. | | | | 77019 | N05769 | D081 |
| Kit Exp Date | | | | 31May99 | 31July11 | 22Jan11 |

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.

POS=positive; NEG=negative; BLD=below the limit of detection; ALR=above linear range; NA=not applicable; f=faint; IND=Indeterminate
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare

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HIV Antigen (s/co)²

| Panel Member | Bleed Date | Days Since 1 st Bleed | Abbott HIVAg-1 Monoclonal EIA | COULTER HIV-1 p24 Antigen | Innogenetics HIV-1 p24 Antigen ELISA | Perkin Elmer HIVAg p24 |
|---------------|------------|----------------------------------|-------------------------------|---------------------------|--------------------------------------|------------------------|
| PRB956-01 | 03-Jul-97 | 0 | 0.3 | 0.3 | 0.3 | 0.3 |
| PRB956-02 | 12-Aug-97 | 40 | 0.4 | 0.3 | 0.4 | 0.3 |
| PRB956-03 | 14-Aug-97 | 42 | 0.3 | 0.3 | 0.4 | 0.4 |
| PRB956-04 | 19-Aug-07 | 47 | 1.5 | 3.2 | 7.5 | 5.9 |
| PRB956-05 | 22-Aug-97 | 50 | 3.5 | 7.2 | 20.2 | 17.0 |
| Test Date | | | 14Oct99 | 22Oct99 | 28Oct99 | 04Jan11 |
| Test Site | | | SC | SC | SC | SC |
| Kit Part Code | | | 2A81 | 6604535 | K-1048 | NEK050A |
| Kit Lot No. | | | 53321M301 | 2069D904 | 90301289 | 990-101001 |
| Kit Exp Date | | | 29Oct99 | 29Mar00 | 31Jan00 | 01Jun11 |

HIV Antigen/Antibody (s/co)¹

| Panel Member | Bleed Date | Days Since 1 st Bleed | Abbott HIV Ag/Ab ARCHITECT Combo | BioMerieux HIV 1/2 DUO | Bio-Rad Genscreen Ultra HIV Ag/Ab Combo | Dade Behring Enzygnost HIV Integral |
|---------------|------------|----------------------------------|----------------------------------|------------------------|---|-------------------------------------|
| PRB956-01 | 03-Jul-97 | 0 | 0.2 | 0.3 | 0.5 | 0.0 |
| PRB956-02 | 12-Aug-97 | 40 | 0.1 | 0.3 | 0.5 | 0.0 |
| PRB956-03 | 14-Aug-97 | 42 | 0.3 | 0.4 | 0.5 | 0.0 |
| PRB956-04 | 19-Aug-07 | 47 | 3.7 | 1.3 | 2.6 | 0.3 |
| PRB956-05 | 22-Aug-97 | 50 | 13.9 | 2.8 | 6.2 | 1.5 |
| Test Date | | | 25Jan11 | 19Nov99 | 21Jan11 | 17Nov99 |
| Test Site | | | RL | RL | SC | RL |
| Kit Part Code | | | 2P36-10 | 30114 | 72386 | OQTO11 |
| Kit Lot No. | | | 92447HN00 | 735175301 | OG0058 | 30769 |
| Kit Exp Date | | | 19Apr11 | 27Aug00 | 30Dec11 | 28Dec99 |

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

POS=positive; NEG=negative; BLD=below the limit of detection; ALR=above linear range; NA=not applicable; f=faint; IND=Indeterminate
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HIV Antigen/Antibody (s/co) ¹

| Panel Member | Bleed Date | Days Since 1 st Bleed | Murex HIV Ag/Ab Combo | Organon Teknika Vironostika HIV Uni-Form II | Roche Enzymun Test HIV Combi |
|---------------|------------|----------------------------------|-----------------------|---|------------------------------|
| PRB956-01 | 03-Jul-97 | 0 | 0.3 | 0.4 | 0.2 |
| PRB956-02 | 12-Aug-97 | 40 | 0.3 | 0.4 | 0.2 |
| PRB956-03 | 14-Aug-97 | 42 | 0.4 | 0.4 | 0.2 |
| PRB956-04 | 19-Aug-07 | 47 | 2.5 | 0.4 | 0.3 |
| PRB956-05 | 22-Aug-97 | 50 | 8.3 | 0.5 | 0.8 |
| Test Date | | | 13Jan11 | 06Dec99 | 15Nov99 |
| Test Site | | | SC | SC | RL |
| Kit Part Code | | | 7G79-11 | 84138 | 1877631 |
| Kit Lot No. | | | L417810 | 99101501 | 19853601 |
| Kit Exp Date | | | 31Mar11 | 30Sep00 | 31Mar01 |

HIV-1 Antibody (s/co) ¹

| Panel Member | Bleed Date | Days Since 1 st Bleed | Abbott HIV-1 EIA | Genetic Systems HIV-1 | Organon Teknika Vironostika® HIV-1 EIA |
|---------------|------------|----------------------------------|------------------|-----------------------|--|
| PRB956-01 | 03-Jul-97 | 0 | 0.2 | 0.1 | 0.3 |
| PRB956-02 | 12-Aug-97 | 40 | 0.2 | 0.1 | 0.3 |
| PRB956-03 | 14-Aug-97 | 42 | 0.2 | 0.1 | 0.3 |
| PRB956-04 | 19-Aug-07 | 47 | 0.2 | 0.1 | 0.3 |
| PRB956-05 | 22-Aug-97 | 50 | 0.2 | 0.1 | 0.3 |
| Test Date | | | 21Oct99 | 21Oct99 | 16Oct99 |
| Test Site | | | SC | SC | SC |
| Kit Part Code | | | 3A11 | 32511 | 59605 |
| Kit Lot No. | | | 55566M201 | 081RAA-05 | 160106 |
| Kit Exp Date | | | 11Nov99 | 10Dec99 | 07Apr00 |

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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HIV-1/2 Antibody (s/co) ¹

| Panel Member | Bleed Date | Days Since 1 st Bleed | Abbott 3rd Generation HIV-1/2 rDNA EIA PLUS | Abbott HIV-1/2 EIA | Abbott AxSYM HIV-1/2 | Abbott PRISM HIV-1/2 | Abbott HIV PRISM |
|----------------------|------------|----------------------------------|---|--------------------|----------------------|----------------------|------------------|
| PRB956-01 | 03-Jul-97 | 0 | 0.2 | 0.1 | 0.4 | 0.3 | 0.3 |
| PRB956-02 | 12-Aug-97 | 40 | 0.3 | 0.1 | 0.5 | 0.3 | 0.4 |
| PRB956-03 | 14-Aug-97 | 42 | 0.2 | 0.1 | 0.4 | 0.3 | 0.4 |
| PRB956-04 | 19-Aug-07 | 47 | 0.2 | 0.1 | 0.4 | 0.2 | 0.4 |
| PRB956-05 | 22-Aug-97 | 50 | 0.7 | 0.8 | 0.5 | 1.0 | 0.9 |
| Test Date | | | 15Nov99 | 13Oct99 | 14Dec99 | 27Oct99 | 24Feb11 |
| Test Site | | | RL | SC | RL | RL | RL |
| Kit Part Code | | | 7A84 | 3A77 | 9A44 | 4A27 | 3L68-68 |
| Kit Lot No. | | | 57381HP00 | 53640M301 | 59152LU00 | 57376HP00 | 93390M500 |
| Kit Exp Date | | | 04May00 | 22Oct99 | 14Apr00 | 22May00 | 03Sep11 |

HIV-1/2 Antibody (s/co) ¹

| Panel Member | Bleed Date | Days Since 1 st Bleed | Bio-Rad HIV-1/HIV-2 Plus O Gen Sys | Diag. Past. Access HIV-1/2 | Diag. Past. Genscreen HIV-1/2 | Fujirebio Serodia HIV-1/2 | Genetic Systems HIV-1/2 Peptide EIA |
|----------------------|------------|----------------------------------|------------------------------------|----------------------------|-------------------------------|---------------------------|-------------------------------------|
| PRB956-01 | 03-Jul-97 | 0 | 0.1 | 0.2 | 0.1 | - | 0.2 |
| PRB956-02 | 12-Aug-97 | 40 | 0.1 | 0.3 | 0.1 | - | 0.1 |
| PRB956-03 | 14-Aug-97 | 42 | 0.1 | 0.2 | 0.1 | - | 0.1 |
| PRB956-04 | 19-Aug-07 | 47 | 0.1 | 0.2 | 0.1 | - | 0.1 |
| PRB956-05 | 22-Aug-97 | 50 | 0.6 | 0.3 | 2.2 | +/- | 0.2 |
| Test Date | | | 20Dec10 | 01Dec99 | 03Nov99 | 03Nov99 | 16Oct99 |
| Test Site | | | SC | RL | RL | RL | SC |
| Kit Part Code | | | 32588 | 3400 | 72278 | 71110 | 32551 |
| Kit Lot No. | | | 209EBB-05 | 994649 | 9HO16U | M281204 | 153RP1-05 |
| Kit Exp Date | | | 15Apr11 | 15May00 | 31Aug00 | 21Dec99 | 15Apr00 |

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

POS=positive; NEG=negative; BLD=below the limit of detection; ALR=above linear range; NA=not applicable ; f=faint; IND=Indeterminate
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare

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HIV-1/2 Antibody (s/co) ¹

| Panel Member | Bleed Date | Days Since 1 st Bleed | Murex / Wellcozyme HIV-1.2.O | Ortho HIV-1/2 Ab-Capture ELISA | Ortho HIV-1/HIV-2 Vitros Eci | Ortho HIV-1/HIV-2 Vitros Eci | Roche DAGS | Siemens HIV1/O/2 Enhanced Advia Centaur |
|---------------|------------|----------------------------------|------------------------------|--------------------------------|------------------------------|------------------------------|------------|---|
| PRB956-01 | 03-Jul-97 | 0 | 0.3 | 0.0 | 0.1 | 0.1 | 0.2 | 0.1 |
| PRB956-02 | 12-Aug-97 | 40 | 0.3 | 0.0 | 0.1 | 0.2 | 0.2 | 0.1 |
| PRB956-03 | 14-Aug-97 | 42 | 0.3 | 0.0 | 0.1 | 0.1 | 0.3 | 0.2 |
| PRB956-04 | 19-Aug-07 | 47 | 0.5 | 0.2 | 0.2 | 0.4 | 0.2 | 0.2 |
| PRB956-05 | 22-Aug-97 | 50 | 2.9 | 2.2 | 2.1 | 3.7 | 0.7 | 1.5 |
| Test Date | | | 14Oct99 | 26Oct99 | 01Nov99 | 14Jan11 | 16Nov99 | 07Feb11 |
| Test Site | | | SC | RL | RL | RL | RL | RL |
| Kit Part Code | | | GE94 | 932360 | 124 1850 | 6801861 | 756059 | 01463908 |
| Kit Lot No. | | | F796210 | HVK130-2 | 71 | 0370 | B1033 | C071 |
| Kit Exp Date | | | 28Feb00 | 09Dec99 | 23May00 | 30Jun11 | 30Apr00 | 28Apr11 |

Anti-HIV-1 Confirmatory

| Panel Member | Bleed Date | Days Since 1 st Bleed | Bio-Rad Western Blot Band Pattern | Bio-Rad Western Blot Result |
|---------------|------------|----------------------------------|-----------------------------------|-----------------------------|
| PRB956-01 | 03-Jul-97 | 0 | No Bands | NEG |
| PRB956-02 | 12-Aug-97 | 40 | No Bands | NEG |
| PRB956-03 | 14-Aug-97 | 42 | No Bands | NEG |
| PRB956-04 | 19-Aug-07 | 47 | No Bands | NEG |
| PRB956-05 | 22-Aug-97 | 50 | No Bands | NEG |
| Test Date | | | | 15Nov99 |
| Test Site | | | | SC |
| Kit Part Code | | | | 1970001 |
| Kit Lot No. | | | | 97165501 |
| Kit Exp Date | | | | 24Feb00 |

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.

POS=positive; NEG=negative; BLD=below the limit of detection; ALR=above linear range; NA=not applicable ; f=faint; IND=Indeterminate
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare

A printed PI and Data Sheet may be requested by email to info@seracare.com, or by phone to 508.244.6400