OVERVIEW

PRB976 is a four member HIV Seroconversion Panel collected from a single donor over a 9 day period in 1999, prior to antibody seroconversion. Member 2 is a potentially challenging sample for HIV antigen and Ag/Ab tests, and the panel clearly demonstrates improvement in sensitivity with the introduction of the ‘4th generation’ HIV Ag/Ab tests.

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

CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were found positive for markers of HIV infection; all were found negative for HBsAg and anti-HCV.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare does not claim that others can duplicate test results exactly.

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.
### HIV RNA (copies/mL)

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Bleed Date</th>
<th>Days Since 1st Bleed</th>
<th>Fiebig Stage</th>
<th>Abbott RealTime HIV-1 RNA m2000</th>
<th>Roche COBAS® AmpliPrep COBAS® TaqMan® HIV-1 Test v 2.0</th>
<th>Siemens Versant® HIV-1 RNA 3.0 Assay (bDNA)</th>
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<tbody>
<tr>
<td>PRB976-01</td>
<td>04-Nov-99</td>
<td>0</td>
<td>I</td>
<td>7.4 x 10^3</td>
<td>1.6 x 10^4</td>
<td>3.9 x 10^4</td>
</tr>
<tr>
<td>PRB976-02</td>
<td>06-Nov-99</td>
<td>2</td>
<td>I</td>
<td>1.2 x 10^4</td>
<td>3.0 x 10^4</td>
<td>7.4 x 10^4</td>
</tr>
<tr>
<td>PRB976-03</td>
<td>11-Nov-99</td>
<td>7</td>
<td>II</td>
<td>6.1 x 10^5</td>
<td>6.5 x 10^5</td>
<td>2.5 x 10^5</td>
</tr>
<tr>
<td>PRB976-04</td>
<td>13-Nov-99</td>
<td>9</td>
<td>II</td>
<td>1.5 x 10^6</td>
<td>2.3 x 10^5</td>
<td>&gt;5.0 x 10^5</td>
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**Test Date**: 3-Feb-12 | 24-Jan-12 | 1-Feb-12
**Test Site**: RL | SC | RL
**Kit Part Code**: 6L18 | 05212308190 | P07463
**Kit Lot No.**: 10055501 | D088
**Kit Exp. Date**: 31-Dec-12 | 31-Aug-12 | 6-Jun-12
**Kit Regulatory Status**: IVD | IVD | IVD


### HIV Antigen

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Bleed Date</th>
<th>Days Since 1st Bleed</th>
<th>bioMerieux VIDAS HIV p24 II pg/mL</th>
<th>Perkin Elmer Alliance HIV-1 p24 Ag ELISA s/co²</th>
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<tbody>
<tr>
<td>PRB976-01</td>
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<td>&lt;3.0</td>
<td>0.7</td>
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<td>PRB976-02</td>
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<tr>
<td>PRB976-03</td>
<td>11-Nov-99</td>
<td>7</td>
<td>227.9</td>
<td>42.8</td>
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<tr>
<td>PRB976-04</td>
<td>13-Nov-99</td>
<td>9</td>
<td>&gt;400</td>
<td>&gt;50.8</td>
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</table>

**Test Date**: 12-Mar-12 | 1-Feb-12
**Test Site**: RL | SC
**Kit Part Code**: 30117 | NEK050A
**Kit Lot No.**: 120507-0 | 990-11521
**Kit Exp. Date**: 17-Jul-12 | 1-Oct-12
**Kit Regulatory Status**: CE | RUO

1 Quantitative HIV Antigen results are means of duplicates expressed in pg/mL. Results ≥3.0 are considered reactive and noted in red.
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.

POS = positive; NEG = negative; BLD = below the limit of detection; IND = indeterminate; NA = not available, NT = not tested
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare

ASR = analyte specific reagent; CE = Conformité Européenne or CE Marking; IVD = for in vitro diagnostic use; LDT = laboratory developed test; RUO = research use only
### HIV Antigen/Antibody (s/co)¹

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Bleed Date</th>
<th>Days Since 1st Bleed</th>
<th>Abbott HIV Ag/Ab ARCHITECT Combo</th>
<th>Abbott HIV Ag/Ab AxSYM Combo</th>
<th>Abbott HIV Ag/Ab PRISM Combo</th>
<th>Bio-Rad Genscreen Ultra HIV Ag/Ab Combo</th>
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<td>PRB976-01</td>
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<td>0.4</td>
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<td>0.7</td>
<td>0.4</td>
<td>0.5</td>
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<td>15.4</td>
<td>25.9</td>
<td>10.3</td>
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<td>72.6</td>
<td>26.4</td>
<td>42.1</td>
<td>&gt;11.9</td>
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**Test Date**
- 6-Feb-12
- 8-Feb-12
- 16-Feb-12
- 16-Mar-12

**Test Site**
- RL
- RL
- RL
- SC

**Kit Part Code**
- 4J27
- 2G83
- 7G46-48
- 72386

**Kit LOT No.**
- 08413L100
- 11457LF00
- 12312L100
- 1C1067

**Kit Exp. Date**
- 30-Apr-12
- 16-May-12
- 17-Nov-12
- 30-Aug-12

**Kit Regulatory Status**
- CE   
- CE   
- CE   

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.

### HIV Antigen/Antibody

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Bleed Date</th>
<th>Days Since 1st Bleed</th>
<th>Bio-Rad GS HIV Combo Ag/Ab EIA s/co¹</th>
<th>Murex HIV Ag/Ab Combination s/co²</th>
<th>Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ag</th>
<th>Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ab</th>
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<tbody>
<tr>
<td>PRB976-01</td>
<td>04-Nov-99</td>
<td>0</td>
<td>0.1</td>
<td>0.6</td>
<td>NEG</td>
<td>NEG</td>
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<tr>
<td>PRB976-02</td>
<td>06-Nov-99</td>
<td>2</td>
<td>0.7</td>
<td>0.6</td>
<td>NEG</td>
<td>NEG</td>
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<tr>
<td>PRB976-03</td>
<td>11-Nov-99</td>
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<td>&gt;11.7</td>
<td>17.0</td>
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<td>NEG</td>
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<td>&gt;11.7</td>
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<td>NEG</td>
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**Test Date**
- 15-Feb-12
- 16-Feb-12
- 5-Mar-12

**Test Site**
- SC
- RL
- SC

**Kit Part Code**
- 26217
- GE41/42
- 7D26-46

**Kit Exp. Date**
- 27-Sep-12
- 31-Jan-13
- 11-Nov-12

**Kit Regulatory Status**
- IVD  
- CE  
- CE  

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

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## HIV Antibody (s/co)\(^1\)

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Bleed Date</th>
<th>Days Since 1(^{st}) Bleed</th>
<th>Avioq HIV-1 Microelisa System</th>
<th>Bio-Rad GS HIV-1/HIV-2 Plus O EIA</th>
<th>Siemens HIV 1/O/2 Enhanced ADVIA Centaur</th>
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<tr>
<td>PRB976-01</td>
<td>04-Nov-99</td>
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<td>0.1</td>
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<td>2</td>
<td>0.2</td>
<td>0.1</td>
<td>&lt;0.05</td>
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<tr>
<td>PRB976-03</td>
<td>11-Nov-99</td>
<td>7</td>
<td>0.2</td>
<td>0.3</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>PRB976-04</td>
<td>13-Nov-99</td>
<td>9</td>
<td>0.2</td>
<td>0.3</td>
<td>&lt;0.05</td>
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Test Date: 1-Feb-12 31-Jan-12 7-Feb-12
Test Site: SC SC RL
Kit Part Code: 100384 32588 01622429
Kit Lot No.: J2299 279FBB-05 82415114
Kit Exp. Date: 12-Oct-12 15-May-12 20-Apr-12
Kit Regulatory Status: IVD IVD IVD

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

## HIV Confirmatory

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Bleed Date</th>
<th>Days Since 1(^{st}) Bleed</th>
<th>Bio-Rad GS HIV-1 Western Blot Band Pattern</th>
<th>Bio-Rad GS HIV-1 Western Blot Result</th>
<th>Calypte/ MAXIM HIV-1 Western Blot Band Pattern</th>
<th>Calypte/ MAXIM HIV-1 Western Blot Result</th>
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<tbody>
<tr>
<td>PRB976-01</td>
<td>04-Nov-99</td>
<td>0</td>
<td>No Bands</td>
<td>Neg</td>
<td>No Bands</td>
<td>Neg</td>
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<tr>
<td>PRB976-02</td>
<td>06-Nov-99</td>
<td>2</td>
<td>No Bands</td>
<td>Neg</td>
<td>No Bands</td>
<td>Neg</td>
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<tr>
<td>PRB976-03</td>
<td>11-Nov-99</td>
<td>7</td>
<td>No Bands</td>
<td>Neg</td>
<td>No Bands</td>
<td>Neg</td>
</tr>
<tr>
<td>PRB976-04</td>
<td>13-Nov-99</td>
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<td>No Bands</td>
<td>Neg</td>
<td>No Bands</td>
<td>Neg</td>
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Test Date: 9-Feb-12 6-Feb-12
Test Site: SC SC
Kit Part Code: 1971101 98002
Kit Lot No.: 109338 A2322-227
Kit Exp. Date: 24-Jun-12 17-Nov-12
Kit Regulatory Status: IVD IVD

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## HIV Confirmatory

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Bleed Date</th>
<th>Days Since 1st Bleed</th>
<th>Innogenetics INNO-LIA™ HIV I/II Band Pattern</th>
<th>Innogenetics INNO-LIA™ HIV I/II Result</th>
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</thead>
<tbody>
<tr>
<td>PRB976-01</td>
<td>04-Nov-99</td>
<td>0</td>
<td>No Bands</td>
<td>NEG</td>
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<tr>
<td>PRB976-02</td>
<td>06-Nov-99</td>
<td>2</td>
<td>No Bands</td>
<td>NEG</td>
</tr>
<tr>
<td>PRB976-03</td>
<td>11-Nov-99</td>
<td>7</td>
<td>No Bands</td>
<td>NEG</td>
</tr>
<tr>
<td>PRB976-04</td>
<td>13-Nov-99</td>
<td>9</td>
<td>No Bands</td>
<td>NEG</td>
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**Test Date:** 12-Mar-12  
**Test Site:** RL  
**Kit Part Code:** INX22206  
**Kit Lot No.:** 220376  
**Kit Exp. Date:** 31-Jan-13  
**Kit Regulatory Status:** CE

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- 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

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