

**OVERVIEW**

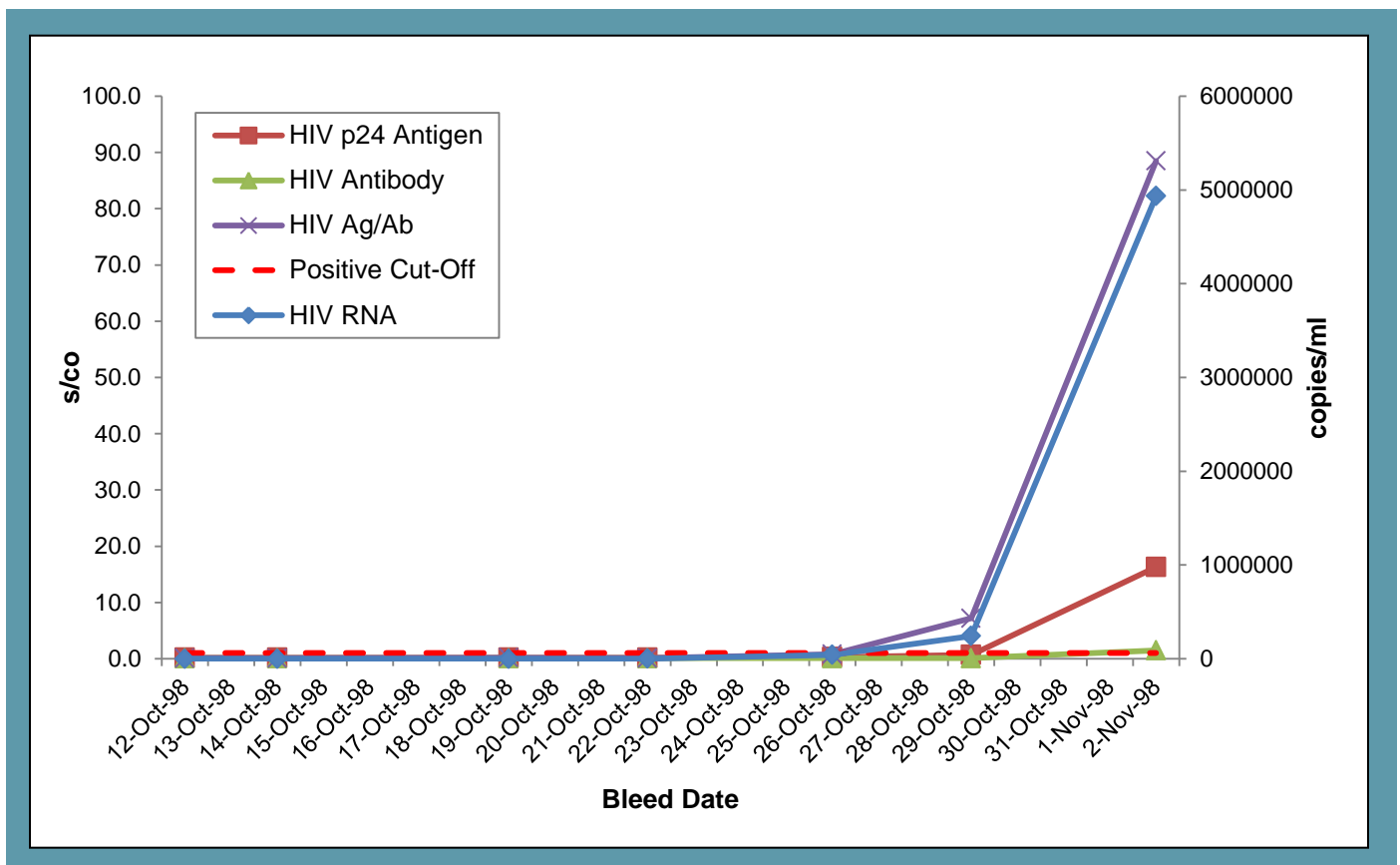
HIV-1 AccuVert™ Seroconversion Performance Panel is a 7-member panel of undiluted, naturally-occurring plasma samples collected from a single donor over 21 days (1 vial per member, 1.0 mL per vial). Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV assays are included for characterization of the panel members. This panel of human plasma samples converts from negative to positive for HIV antibody, p24 antigen, and HIV-1 RNA.

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.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested for HBsAg and anti-HCV and found to be negative. This does not ensure the absence of these or other human pathogens.

**Progression of HIV Markers in Early Infection**



*This graph demonstrates the progression of HIV markers amongst panel members utilizing test results from the Roche COBAS® Ampliprep/COBAS® TaqMan® HIV-1 RNA Test v2.0, Zepmetrix HIV Type 1 p24 Antigen ELISA, Bio-Rad Genetic Systems™ HIV-1/HIV-2 Plus O EIA, and Abbott ARCHITECT HIV Ag/Ab Combo Assay.*

# HIV-1 AccuVert™ Seroconversion Panel PRB954 (0600-0238)

## DATA SHEET

### HIV-1 RNA<sup>1</sup>

Panel Member	Bleed Date	Days Since 1st Bleed	Roche COBAS® AmpliPrep/COBAS®		Chiron 3.0 bDNA	Org. Tek. NASBA	Roche RT-PCR
			TaqMan® HIV-1 Test, v2.0 <sup>2</sup>				
01	12-Oct-98	0	Not Detected		BLD	BLD	BLD
02	14-Oct-98	2	Not Detected		BLD	BLD	BLD
03	19-Oct-98	7	Not Detected		BLD	BLD	BLD
04	22-Oct-98	10	<b>953</b>		<b>600</b>	BLD	<b>1000</b>
05	26-Oct-98	14	<b>42081</b>		<b>30000</b>	<b>20000</b>	<b>60000</b>
06	29-Oct-98	17	<b>243211</b>		<b>300000</b>	<b>200000</b>	<b>600000</b>
07	02-Nov-98	21	<b>4935470</b>		<b>&gt;500000</b>	<b>&gt;1000000</b>	<b>&gt;800000</b>
Test Date			02-Jan-15		28-Apr-99	29-Apr-99	12-Apr-99
Test Site			RL		SC	SC	SC
Kit Part Code			NA		116147	84043	83088
Kit Lot No.			NA		Z005H	99021209	88809
Kit Exp. Date			NA		07-Jun-99	Feb-00	Jun-99

BLD = Below the limit of detection, SC = SeraCare, RL = Reference Lab  
<sup>1</sup>HIV-1 RNA results are single observations, expressed as RNA copies/mL.  
<sup>2</sup>Kit regulatory status = FDA and CE approved.

### HIV-1 p24 Antigen<sup>1,2</sup>

Panel Member	Bleed Date	Days Since 1st Bleed	Zeptomatrix HIV Type 1 p24 Antigen		Zeptomatrix HIV Ag	Innogenetics Innotest	Abbott Monoclonal	Coulter HIV Ag
			ELISA <sup>3</sup>	Perkin Elmer				
01	12-Oct-98	0	0.2	0.1	0.1	0.2	0.3	0.5
02	14-Oct-98	2	0.2	0.1	0.1	0.3	0.3	0.4
03	19-Oct-98	7	0.2	0.1	0.2	0.3	0.3	0.3
04	22-Oct-98	10	0.2	0.1	0.2	0.3	0.3	0.3
05	26-Oct-98	14	0.3	0.9	0.6	0.9	0.5	0.3
06	29-Oct-98	17	0.7	<b>9.9</b>	<b>3.8</b>	<b>8.8</b>	<b>2.1</b>	0.6
07	02-Nov-98	21	<b>16.3</b>	<b>52.6</b>	<b>40.3</b>	<b>&gt;29.1</b>	<b>23.1</b>	<b>3.1</b>
Test Date			11-Aug-14	22-May-08	20-May-08	05-May-99	28-Apr-99	12-May-99
Test Site			SC	SC	SC	SC	SC	SC
Kit Part			0801111	NEK050A	801111	K-1048	2A81	6604535
Kit Lot No.			312548	465436	303872	71215921-B	49710M301	2068L744
Kit Exp. Date			21-Mar-15	17-Feb-09	27-Nov-08	Jul-99	23-May-99	28-Aug-99

SC = SeraCare  
<sup>1</sup>Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.  
<sup>2</sup>Results are reported as the mean result of duplicate testing.  
<sup>3</sup>Kit regulatory status = Research Use Only (RUO).

# HIV-1 AccuVert™ Seroconversion Panel PRB954 (0600-0238)

## DATA SHEET

### HIV-1/2 Antibody<sup>1,2</sup>

Panel Member	Bleed Date	Days Since 1st Bleed	Bio-Rad Genetic Systems™ HIV-1/HIV-2 Plus O EIA <sup>3</sup>	Abbott HIV	Abbott HIV-1/2	Genetic Systems HIV	Bio-Rad HIV-1/2	Org. Tek HIV
01	12-Oct-98	0	0.1	0.2	0.1	0.1	0.1	0.4
02	14-Oct-98	2	0.1	0.2	0.1	0.1	0.1	0.4
03	19-Oct-98	7	0.1	0.2	0.3	0.1	0.2	0.4
04	22-Oct-98	10	0.1	0.2	0.2	0.1	0.1	0.4
05	26-Oct-98	14	0.1	0.2	0.1	0.1	0.1	0.4
06	29-Oct-98	17	0.1	0.2	0.1	0.1	0.1	0.4
07	02-Nov-98	21	<b>1.5</b>	0.2	0.8	0.1	<b>2.4</b>	0.5
Test Date			26-Dec-14	28-Apr-99	27-Apr-99	27-Apr-99	20-May-08	28-Apr-99
Test Site			SC	SC	SC	SC	SC	SC
Kit Part Code			32588	3A11	3A77	32511	32588	59605
Kit Lot No.			163JBB-05	50839M301	49014M401	282QAA-05	348BBB-05	160099
Kit Exp. Date			31-Mar-15	03-Jun-99	16-Jun-99	10-Sep-99	20-Aug-08	21-Nov-99

SC = SeraCare

<sup>1</sup>Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as the mean result of duplicate testing.

<sup>3</sup>Kit regulatory status = FDA and CE approved.

### HIV-1/2 Antibody<sup>1,2</sup>

Panel Member	Bleed Date	Days Since 1st Bleed	Abbott 3rd Gen. PLUS	Abbott AxSYM	Abbott PRISM	Diag. Past. Access	Diag. Past. Genscreen	Murex HIV 1.2.O
01	12-Oct-98	0	0.2	0.4	0.4	0.3	0.1	0.4
02	14-Oct-98	2	0.2	0.3	0.4	0.2	0.1	0.3
03	19-Oct-98	7	0.2	0.4	0.6	0.3	0.3	0.5
04	22-Oct-98	10	0.2	0.4	0.4	0.2	0.1	0.3
05	26-Oct-98	14	0.3	0.3	0.4	0.2	0.1	0.3
06	29-Oct-98	17	0.1	0.3	0.4	0.3	0.1	0.3
07	02-Nov-98	21	0.7	0.7	<b>1.0</b>	0.3	<b>12.0</b>	<b>2.2</b>
Test Date			20-May-99	18-May-99	20-May-99	21-May-99	11-May-99	28-Apr-99
Test Site			RL	RL	RL	RL	RL	RL
Kit Part Code			7A84	9A44	4A27	34000	72278	GE94
Kit Lot No.			5120HP00	52750LU00	50233HP00	894647	9D011U	F786210
Kit Exp. Date			30-Oct-99	24-Oct-99	16-Sep-99	01-Oct-99	01-Mar-00	28-Sep-99

RL = Reference Lab

<sup>1</sup>Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as the mean result of duplicate testing.

DATA SHEET

HIV-1/2 Antibody<sup>1,2</sup>

Panel Member	Bleed Date	Days Since 1st Bleed	Ortho Capture	Ortho Vitros Eci	Roche DAGS	Sanofi Fujirebio HIV-1/2 PA
01	12-Oct-98	0	0.0	0.1	0.1	-
02	14-Oct-98	2	0.0	0.1	0.1	-
03	19-Oct-98	7	0.1	0.1	0.1	-
04	22-Oct-98	10	0.0	0.1	0.1	-
05	26-Oct-98	14	0.0	0.1	0.1	-
06	29-Oct-98	17	0.0	0.1	0.1	-
07	02-Nov-98	21	<b>7.5</b>	<b>3.9</b>	<b>1.4</b>	<b>+</b>
Test Date			12-May-99	17-Jun-99	07-Jun-99	20-May-99
Test Site			RL	RL	RL	RL
Kit Part Code			932360	1241850	756059	71110
Kit Lot No.			HVK126-2	30	B1032	M281204
Kit Exp. Date			Jul-99	20-Aug-99	30-Apr-01	21-Dec-99

RL = Reference Lab

<sup>1</sup>Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as the mean result of duplicate testing.

HIV Western Blot<sup>1</sup>

Panel Member	Bleed Date	Days Since 1st Bleed	Cambridge Biotech Western Blot	
			Band Pattern	BandResult
01	12-Oct-98	0	No Bands	Negative
02	14-Oct-98	2	No Bands	Negative
03	19-Oct-98	7	No Bands	Negative
04	22-Oct-98	10	No Bands	Negative
05	26-Oct-98	14	No Bands	Negative
06	29-Oct-98	17	No Bands	Negative
07	02-Nov-98	21	No Bands	Negative
Test Date			06-Apr-99	
Test Site			SC	
Kit Part Code			98002	
Kit Lot No.			A9224-224	
Kit Exp. Date			12-Aug-99	

<sup>1</sup>Western Blots are interpreted using ASTPHLD/CDC criteria (MMWR, vol. 38, S-7, 1989).

# HIV-1 AccuVert™ Seroconversion Panel PRB954 (0600-0238)

## DATA SHEET

### HIV Antigen/Antibody<sup>1,2</sup>

Panel Member	Bleed Date	Days Since 1st Bleed	Abbott ARCHITECT HIV Ag/Ab Combo <sup>3</sup>	BioMerieux Vidas DUO	Dade Behring Integral	Org. Tek Uni-Form II	Roche Enzymun-Test
01	12-Oct-98	0	0.1	0.3	0.0	0.3	0.1
02	14-Oct-98	2	0.1	0.3	0.0	0.4	0.1
03	19-Oct-98	7	0.2	0.3	0.1	0.4	0.2
04	22-Oct-98	10	0.1	0.3	0.0	0.3	0.1
05	26-Oct-98	14	0.8	0.5	0.1	0.4	0.1
06	29-Oct-98	17	<b>7.2</b>	<b>1.9</b>	0.1	0.4	0.3
07	02-Nov-98	21	<b>88.5</b>	<b>18.5</b>	<b>2.5</b>	<b>1.8</b>	<b>4.1</b>
Test Date			31-Dec-14	18-May-99	14-Jun-99	20-May-99	13-Jul-99
Test Site			SC	RL	RL	RL	RL
Kit Part Code			2P36	30114	OQTO11	84138	1877631
Kit Lot No.			44744LI00	7233488201	30769	98072808	19823601
Kit Exp. Date			26-Jul-15	03-Sep-99	22-Jun-99	Jul-99	31-Mar-01

RL = Reference Lab

<sup>1</sup>Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as the mean result of duplicate testing.

<sup>3</sup>Kit regulatory status = FDA and CE approved.

The Package Insert for this panel in PDF form can be found at [www.seracare.com](http://www.seracare.com)

A printed copy of the Package Insert or Data Sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

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