

OVERVIEW

HIV-1 AccuVert[™] Seroconversion Panel 0600-0227 (PRB946) is a 4-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent serial bleeds collected from a single patient over the course of 11 days during the development of an HIV infection and subsequent response. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV assays are included for the characterization of each panel member. This panel of human plasma samples demonstrates a change in expression from negative to positive for HIV-1 RNA and HIV-1 antigen.

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 and found negative for HBsAg and HCV. This does not ensure the absence of these or other human pathogens.

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date*	Days Since 1st Bleed
01	10000671	NA	17Dec1996	0
02	10000670	NA	21Dec1996	4
03	10000668	NA	24Dec1996	7
04	10000669	NA	28Dec1996	11

* An additional specimen from the same donor was collected on April 4, 1997 (day 108) and found to be strongly reactive on Abbott HIV 1/2 and Genetic Systems HIV 1/2 EIA assays with the following bands on Ortho/Cambridge HIV 1 Western Blot: 18, 24, 31, 41, 51, 55, 65, 120, 160 NA – Not available



HIV-1 RNA¹

	Roche PCR	Chiron bDNA
Panel Member	(c/mL) ^{2,3}	(c/mL) ^{2,3}
01	BLD	BLD
02	3 x 10 ⁴	1 x 10 ⁴
03	7 x 10 ⁵	6 x 10 ⁵
04	>8 x 10 ⁵	>8 x 10 ⁵
Test Date	27Mar1997	09May1997
Test Site	BBI	BBI
Kit Part Code	83088	6002-027
Kit Lot No.	88167	MMA279
Kit Exp. Date	30Sep1997	05Jun1997
Kit Regulatory Status	NA	NA

¹ Results are reported as a mean result of duplicate testing.

² Results in bold red are considered positive/reactive.

³ Results are reported in genomic copies per mL (c/mL).

BBI/SCLS = Boston Biomedica Inc. / SeraCare Life Sciences; BLD = Below limit of detection; NA – Not available

HIV-1 Antigen¹

Panel Member	Abbott (s/co) ²	Beckman Coulter (s/co) ²	Dupont (s/co) ²	Innogenetics (s/co) ²	Org. Tek. (s/co) ²	Perkin Elmer (s/co) ²
01	0.4	0.1	0.2	0.4	0.2	0.1
02	0.5	0.8	0.4	1.2	0.3	0.4
03	4.0	23.1	7.9	>35.7	5.4	15.3
04	14.7	>41.7	>28.0	>35.7	15.4	44.9
Test Date	06May1997	07May1997	10May1997	29May1997	06May1997	22May2008
Test Site	BBI	BBI	BBI	RL	BBI	SCLS
Kit Part Code	2A81	933180	NEK-060	K1048	59464	NEK 050A
Kit Lot No.	25780M201	2067A594	189228	61125635	D02400D	465436
Kit Exp. Date	15May1997	12Sep1997	24Jun1997	30Nov1997	21Jan1998	14Feb2009
Kit Regulatory Status	NA	NA	NA	NA	NA	NA

¹ Results are reported as a mean result of duplicate testing.

² Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0. BBI = Boston Biomedica Inc.; SCLS = SeraCare Life Sciences; RL = Reference Laboratory; NA – Not available



Anti-HIV EIA¹

Panel Member	Abbott HIV (s/co) ²	Abbott HIV-1/2 (s/co) ²	Genetic Systems HIV (s/co) ²	Genetic Systems HIV-1/2 (s/co) ²	Org. Tek. HIV (s/co) ²
01	0.2	0.0	0.5	0.2	0.3
02	0.2	0.0	0.5	0.2	0.3
03	0.2	0.1	0.4	0.2	0.3
04	0.2	0.1	0.5	0.2	0.3
Test Date	02May1997	01May1997	05May1997	03May1997	06May1997
Test Site	BBI	BBI	BBI	BBI	BBI
Kit Part Code	3A11	3A77	0218-02	0230	59605
Kit Lot No.	26903M101	26746M201	341NX1-05	073PR1-05	160056
Kit Exp. Date	14May1997	29Jul1997	17Jul1997	16Jan1998	10Apr1998
Kit Regulatory Status	IVD	IVD	IVD	IVD	IVD

¹ Results are reported as a mean result of duplicate testing.

² Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0. BBI = Boston Biomedica Inc. ; IVD = In Vitro Diagnostic



Anti-HIV 1/2¹

Panel Member	Abbott 3 rd Gen. (s/co) ⁴	Abbott 3 rd Gen. PLUS (s/co) ²	Abbott AxSYM (s/co) ²	Behring ENZ PLUS (s/co) ²
01	0.1	0.4	0.4	0.1
02	0.1	0.4	0.4	0.1
03	0.1	0.4	0.5	0.1
04	0.3	0.5	0.5	0.2
Test Date	13May1997	12May1997	26May1997	21May1997
Test Site	RL	RL	RL	RL
Kit Part Code	3A10	7A84	9A44	OQFK
Kit Lot No.	26758M201	27448 HP 00	28382 LU 04	29085
Kit Exp. Date	17Aug1997	11Sep1997	14Oct1997	05Feb1998
Kit Regulatory Status	CE	CE	CE	CE

¹ Results are reported as a mean result of duplicate testing.

² Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0. RL = Reference Laboratory; CE = Conformité Européenne or CE Marking

Anti-HIV 1/2¹

Panel Member	BioChem Detect HIV (s/co) ²	Biotest HIV 1/2 (s/co) ²	Boeh. Mann. Enzymun Gen. 3 (s/co) ²	Diag. Past. Genscreen (s/co) ²
01	0.1	0.1	0.2	0.3
02	0.1	0.1	0.3	0.3
03	0.1	0.0	0.2	0.4
04	0.0	0.1	0.2	0.7
Test Date	03May1997	08May1997	07May1997	22May1997
Test Site	BBI	RL	BBI	RL
Kit Part Code	RHD-902B	807005	1557319	72276
Kit Lot No.	11159-2	123116	190583-01	7A109U
Kit Exp. Date	30Jun1997	19Jul1997	30Sep1997	15Dec1997
Kit Regulatory Status	CE	CE	CE	CE

¹ Results are reported as a mean result of duplicate testing.

² Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0.

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Anti-HIV 1/2¹

Panel Member	Innogenetics Innotest (s/co) ²	Murex/Well. HIV 1/2 (s/co) ²	Murex ICE HIV 1.O.2 (s/co) ²	Org. Tek. Uni-form II PLUS (s/co) ²
01	0.0	0.3	0.3	0.4
02	0.0	0.3	0.3	0.4
03	0.0	0.5	0.3	0.5
04	0.0	0.4	0.3	0.5
Test Date	07May1997	08May1997	06May1997	05May1997
Test Site	RL	RL	RL	RL
Kit Part Code	M421	VK55	00A1/A2/A3	80495
Kit Lot No.	6122065	K181510	BP F046210	96091805
Kit Exp. Date	30Mar1998	28Jun1997	28Sep1997	28Aug1997
Kit Regulatory Status	NA	NA	NA	NA

¹ Results are reported as a mean result of duplicate testing.

² Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0. RL = Reference Laboratory; NA – Not available

Anti-HIV 1/2¹

Panel Member	Ortho Capture (s/co) ²	In House IgA (s/co) ²	In House IgM (s/co) ²
01	0.0	0.2	0.2
02	0.0	0.3	0.2
03	0.0	0.3	0.2
04	0.1	0.3	0.3
Test Date	28May1997	12May1997	12May1997
Test Site	RL	RL	RL
Kit Part Code	932360	In House	In House
Kit Lot No.	HVK 103-2	NA	NA
Kit Exp. Date	16Jun1997	19Aug1997	19Aug1997
Kit Regulatory Status	NA	NA	NA

¹ Results are reported as a mean result of duplicate testing.

² Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0.

RL = Reference Laboratory; NA – Not available

Anti-HIV 1 Confirmatory*

Panel Member	BioRad Western Blot Band Patterns	BioRad Western Blot Result	Epitope Western Blot Band Patterns	Epitope Western Blot Results	Ortho/Cambridge Western Blot Band Patterns	Ortho/Cambridge Western Blot Results
01	No Bands	NEG	No Bands	NEG	No Bands	NEG
02	No Bands	NEG	No Bands	NEG	No Bands	NEG
03	No Bands	NEG	No Bands	NEG	No Bands	NEG
04	No Bands	NEG	No Bands	NEG	No Bands	NEG
Test Date	2-May-97	2-May-97	6-May-97	6-May-97	8-May-97	8-May-97
Test Site	BBI	BBI	BBI	BBI	BBI	BBI
Kit Part Code	1971101	1971101	72827	72827	PN98002	PN98002
Kit Lot No.	9711013	9711013	M1111601	M1111601	C7209-05	C7209-05
Kit Exp. Date	13-Jul-97	13-Jul-97	31-Oct-97	31-Oct-97	28-Jul-97	28-Jul-97
Kit Regulatory Status	IVD	IVD	IVD	IVD	IVD	IVD

* Western blot are interpreted using the ASTPHLD/CDC criteria (MMWR, vol 38, S-7, 1989).

BBI = Boston Biomedica Inc.; IVD = In Vitro Diagnostic

The package insert for this panel can be found at <u>www.seracare.com</u>

A printed copy of the package insert or data sheet may be requested by email at <u>info@seracare.com</u>, or by phone at 508.244.6400

