

AccuVert[™] HIV-1 Seroconversion Panel PRB949(M) (0600-0230) / Batch #10372218

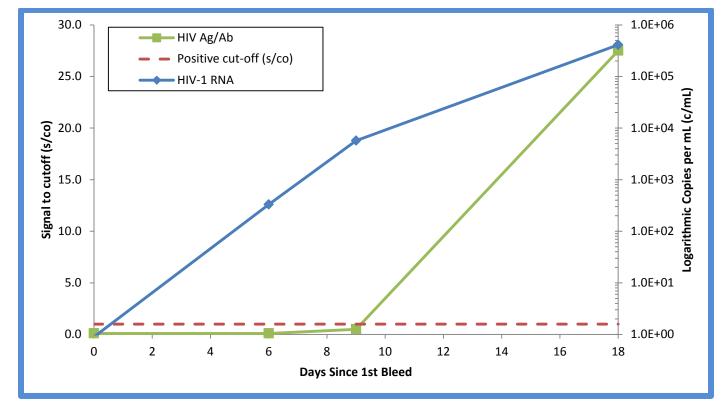
OVERVIEW

AccuVert[™] HIV-1 Seroconversion Panel PRB949M (0605-0230) / Batch #10372218 is a modified 4-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL) collected over 18 days in 1997. Panel Member 05 is no longer available. No preservatives were added.

Test results from commercially-available HIV RNA, antigen, and antibody assays are included for reference. This panel converts from negative to positive for HIV-1 RNA and HIV antigen/antibodies.

For Research Use Only. Not for use in diagnostic procedures. Data are offered 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 anti-HCV. This does not ensure the absence of these or other human pathogens.



Evolution of HIV Markers in Early Infection

This graph demonstrates the evolution of early HIV infection amongst panel members from the Abbott ARCHITECT (HIV Antigen/Antibody) and Roche COBAS (HIV-1 RNA) test methods.



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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Days Since 1 st Bleed
01	10000557	NA	17-Apr-1997	0
02	10000558	NA	23-Apr-1997	6
03	10000559	NA	26-Apr-1997	9
04	10000560	NA	05-May-1997	18
05	NA	NA	NA	NA
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NA = Not Available

Panel Member 05 is no longer available.

HIV RNA and Antigen

Panel Member	Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test v2.0 (c/mL) ¹	Roche Elecsys HIV combi PT (s/co) ^{2,3}	Perkin Elmer Alliance HIV-1 p24 Ag ELISA (s/co) ^{2,3}
01	TND	0.2	0.1
02	3.3 x 10 ²	0.2	0.2
03	5.7 x 10 ³	0.4	0.2
04	4.1 x 10 ⁵	12.2	11.5
05	NT	NT	NT
Test Date	11-Oct-2018	11-Oct-2018	09-Oct-2018
Test Site	RL	RL	SC
Kit Part Code	NA	NA	NEK050A
Kit Lot No.	NA	NA	990-18231
Kit Exp. Date	NA	NA	01-Mar-2019
Kit Regulatory Status	IVD/CE	IVD	RUO

¹Results are reported as copies per mL (c/mL); positive/reactive results are noted in bold red.

²Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

³Results are reported as the mean result of duplicate testing.

NA = Not Available; NT = Not Tested

SC = SeraCare; RL = Reference Lab

IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research Use Only



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HIV Combo, HIV Ag/Ab, HIV Rapid Tests

Panel Member	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA (s/co) ^{1,2}	Abbott PRISM HIV O Plus (s/co) ^{1,2}	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) ^{1,2}	Alere Determine HIV-1/2 Antigen	Alere Determine HIV-1/2 Antibody
01	0.1	0.3	0.1	NEG	NEG
02	0.2	0.4	0.1	NEG	NEG
03	0.1	0.3	0.5	NEG	NEG
04	0.8	0.6	27.5	POS ³	POS ³
05	NT	NT	NT	NT	NT
Test Date	08-Oct-2018	09-Oct-2018	05-Oct-2018	05-Oct-2018	05-Oct-2018
Test Site	SC	RL	SC	SC	SC
Kit Part Code	32588	NA	2P36	7D2648	7D2648
Kit Lot No.	107NBB-05	NA	86157LI00	098341	098341
Kit Exp. Date	30-Nov-2018	NA	15-Dec-2018	23-Aug-2019	23-Aug-2019
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/	IVD/CE	IVD/CE

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

³ Very faint band.

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The package insert for this panel can be found at www.seracare.com.

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.