

### AccuVert™ HIV-1 Seroconversion Panel PRB973 (0600-0256) / Batch #10389479

#### **OVERVIEW**

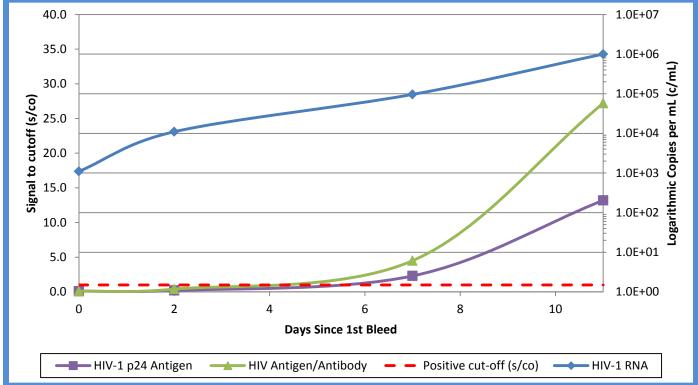
AccuVert™ HIV-1 Seroconversion Panel PRB973 (0600-0256) is a 4-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent serial bleeds collected from a single individual over the course of 11 days during the development of an HIV infection and subsequent response. Each sample represents a single collection event. No preservatives were added.

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

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 positive for markers of HIV infection and negative for HBsAg and HCV. This does not ensure the absence of these or other human pathogens.

# **Evolution of HIV Markers in Early Infection** 40.0



This graph demonstrates the evolution of early HIV infection amongst panel members using the Perkin Elmer (HIV-1 p24 Antigen). Abbott ARCHITECT (HIV-1 Antigen/Antibody), and Roche COBAS (HIV-1 RNA) test methods.

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#### **Panel Member Information**

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Fiebig Stage <sup>1</sup>	Bleed Date	Days Since 1 <sup>st</sup> Bleed
01	9252540	BD110950	1	06-Jun-2000	0
02	9253077	BD110950	I	08-Jun-2000	2
03	9252541	BD110950	II	13-Jun-2000	7
04	9253078	BD110950	III/IV	17-Jun-2000	11

<sup>&</sup>lt;sup>1</sup>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.

**HIV RNA and HIV Antigen** 

Panel Member	Roche COBAS <sup>®</sup> AmpliPrep COBAS <sup>®</sup> TaqMan <sup>®</sup> HIV-1 Test v2.0 (c/mL) <sup>1</sup>	Perkin Elmer Alliance HIV-1 p24 ELISA (s/co) <sup>2,3</sup>
01	1.1 x 10 <sup>3</sup>	0.1
02	1.1 x 10 <sup>4</sup>	0.2
03	9.6 x 10 <sup>4</sup>	2.3
04	1.0 x 10 <sup>6</sup>	13.2
Test Date	24-Jan-2019	21-Jan-2019
Test Site	RL	SC
Kit Part Code	NA	NEK050B
Kit Lot No.	NA	990-18281
Kit Exp. Date	NA	01-Jun-2019
Kit Regulatory Status	IVD/CE	RUO

<sup>&</sup>lt;sup>1</sup>Results are reported as copies per milliliter (c/mL). Positive/reactive results are noted in bold red.

RL = Reference Lab; SC = SeraCare

NA = Not Available

IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research use only

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

<sup>&</sup>lt;sup>3</sup>Results are reported as the mean result of duplicate testing.



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### HIV Antigen/Antibody (s/co)<sup>1,2</sup>

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo	Abbott PRISM HIV Ag/Ab Combo	Roche Elecsys HIV combi PT	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA
01	0.1	0.3	0.2	0.2
02	0.4	0.3	0.3	0.1
03	4.5	0.4	1.7	0.1
04	27.2	2.5	9.4	7.6
Test Date	14-Jan-2019	16-Jan-2019	21-Jan-2019	17-Jan-2019
Test Site	SC	RL	RL	SC
Kit Part Code	2P36	NA	NA	32588
Kit Lot No.	88192LI00	NA	NA	148NBB-05
Kit Exp. Date	12-Feb-2019	NA	NA	31-May-2019
Kit Regulatory Status	IVD/CE	IVD/CE	IVD	IVD

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

NA = Not Available

IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

### **Anti-HIV Confirmatory and Rapid Tests**

Panel Member	Bio-Rad GS HIV-1 Western Blot Band Pattern	Bio-Rad GS HIV-1 Western Blot Result	Alere Determine HIV-1/2 Ag Result	Alere Determine HIV-1/2 Ab Result	
01	No bands	NEG	NEG	NEG	
02	No bands	NEG	NEG	NEG	
03	No bands	NEG	NEG	NEG	
04	f24	IND	NEG	NEG	
Test Date	21-Jan-2019		15-Jan-2019		
Test Site	SC		SC		
Kit Part Code	32508		7D2648		
Kit Lot No.	64190924		098341		
Kit Exp. Date	14-Jun-2019		23-Aug-2019		
Kit Regulatory Status	IVD		IVD/CE		

f = faint band; NEG = Negative; IND - Indeterminate

SC = SeraCare

IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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 <a href="mailto:info@seracare.com">info@seracare.com</a> or by phone at 508.244.6400.

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

RL = Reference Lab; SC = SeraCare