AccuSet™ Anti-HIV-1 Low Titer Performance Panel Modified

PRB109(M) (0800-0301) / Batch #10311491

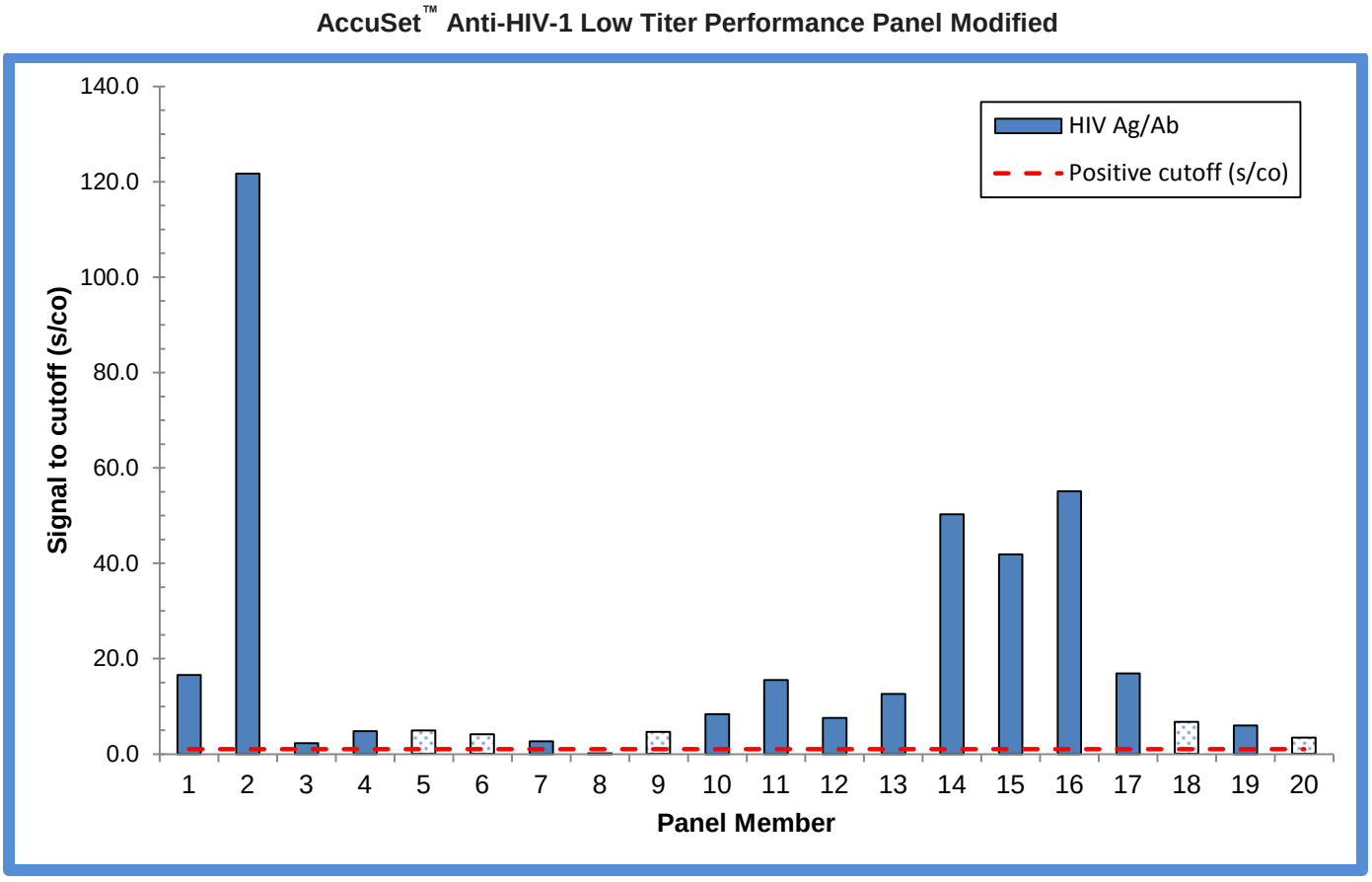
OVERVIEW

AccuSet™ Anti-HIV-1 Low Titer Performance Panel Modified PRB109(M) (0800-0301) / Batch #10311491 is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antigen/antibodies to HIV. 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 demonstrates a range of antibody reactivity which approaches the sensitivity limits for several HIV test methods. One sample is included as a non-reactive sample and is negative for all HIV test methods performed.

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 anti-HCV and HBsAg. This does not ensure the absence of these or other human pathogens.



This graph demonstrates HIV-1 Ag/Ab reactivity amongst panel members utilizing test results from the Abbott Prism HIV Ag/Ab Combo method. Panel members 5, 6, 9, 18 and 20 are no longer available. Data are provided for informational purposes only.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Fiebig Stage[1]
01	BM202249	NA	06-Nov-01	IV
02	BM202261	NA	18-Jan-02	II / III
03	BM202265	NA	18-Feb-02	IV
04	BM202266	NA	20-Feb-02	IV
05	BM202267	NA	02-May-02	IV
06	BM202271	NA	06-Jun-02	IV
07	BM202272	NA	31-May-02	III
08	9178194	NA	31-Jul-03	NA
09	BM202291	NA	22-Oct-02	IV
10	BM206239	BD102670	22-May-06	IV
11	BM206240	BD102670	24-May-06	IV
12	BM202161	BD100797	21-Oct-04	V
13	BM217811	BD105709	14-Sep-07	IV
14	BM217812	BD105709	19-Sep-07	IV
15	BM217813	BD105709	21-Sep-07	V
16	9222531	BD105878	20-Dec-07	IV
17	BM202297	NA	12-Oct-02	IV
18	BM202296	NA	14-Oct-02	V
19	9230846	BD106689	29-Apr-08	V
20	BM202278	NA	13-Jun-02	V

[1]Fiebig stage is assigned according to EW Fiebig at al, Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection.

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NA = Not Available

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HIV RNA and Antigen

Panel Member	Roche Amplicor Monitor HIV-1 RNA (c/mL)	Perkin Elmer HIV Antigen (s/co)[1]	Zeptometrix HIV Antigen (s/co)[1]
01	**5.5×10^5**	**33.2**	**6.2**
02	**4.8×10^6**	**>46.0**	**24.2**
03	**2.3×10^5**	**5.3**	**1.5**
04	**2.7×10^5**	**10.5**	**2.5**
05	**3.2×10^4**	**1.4**	**1.0**
06	**2.3×10^5**	**12.6**	**3.6**
07	**6.2×10^4**	**3.6**	**1.3**
08	BLD	0.3	0.7
09	**2.1×10^5**	**5.3**	**2.4**
10	**1.2×10^5**	**3.5**	**1.3**
11	**5.7×10^5**	**10.6**	**2.4**
12	**4.1×10^5**	**8.7**	**2.4**
13	**5.0×10^5**	**19.7**	**4.2**
14	**2.4×10^6**	**>46.0**	**11.8**
15	**7.0×10^5**	**>46.0**	**8.4**
16	**5.7×10^6**	**>46.0**	**16.5**
17	**1.7×10^5**	**28.0**	**6.8**
18	**7.8×10^4**	**3.7**	**1.3**
19	**2.1×10^4**	0.4	0.7
20	**6.9×10^3**	**1.1**	0.9
Test Date	18-Jun-09, 29-Jun-09	18-Jun-09	16-Jun-09
Test Site	SC	SC	SC
Kit Part Code	83377	NEK 050B	0801111
Kit Lot No.	K10107	990-090302	304824
Kit Exp. Date	31-Oct-09	01-Jan-10	15-Dec-09
Kit Regulatory Status	IVD/CE	RUO	RUO

[1]Ratios ≥1.0 are considered positive/reactive and noted in bold red.
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HIV Antibody (s/co)[1,2]

Panel Member	Abbott HIVAB HIV-1/HIV-2 (rDNA) EIA	Bio-Rad GS HIV-1/HIV-2 Plus O EIA	Genetic Systems HIV-1 rLAV EIA
01	**4.1**	**>10.9**	0.2
02	0.7	**>10.9**	0.1
03	0.6	**8.5**	0.1
04	**2.1**	**>10.9**	0.2
05	**18.4**	**>10.9**	**1.7**
06	**3.6**	**4.1**	**1.2**
07	0.7	**1.3**	0.2
08	0.1	0.1	0.1
09	**2.5**	**>10.9**	0.6
10	**10.3**	**>10.9**	**1.0**
11	**7.4**	**>10.9**	**2.1**
12	**11.8**	**>10.9**	**2.1**
13	0.5	0.3	0.2
14	**10.1**	**>10.9**	**3.1**
15	**7.2**	**>10.9**	**3.9**
16	**6.1**	**>10.9**	0.3
17	**2.2**	**>10.9**	0.4
18	**7.7**	**>10.9**	**1.5**
19	**16.3**	**>10.9**	**3.3**
20	**1.5**	**>10.9**	**2.2**
Test Date	15 Jun 09	15 Jun 09	15 Jun 09
Test Site	SC	SC	SC
Kit Part Code	3A77	32588	32511
Kit Lot No.	76625M100	324CBB	221CAA
Kit Exp. Date	02 Aug 09	13 Aug 09	01 Jul 09
Kit Regulatory Status	IVD	IVD	RUO

[1]EIA results are reported as a signal to cutoff ratio (s/co); Ratios ≥1.0 are considered positive/reactive and noted in bold red.
[2]Results are reported as the mean result of duplicate testing.
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HIV Antigen/Antibody (s/co)[1]

Panel Member	Abbott ARCHITECT Combo HIV Ag/Ab	Abbott PRISM Combo HIV Ag/Ab	Murex Combination EIA HIV Ag/Ab	Roche Elecsys Combi HIV Ag/Ab
01	**40.9**	**16.6**	**17.8**	**8.2**
02	**281.3**	**121.7**	**18.9**	**36.7**
03	**3.5**	**2.3**	**2.8**	**5.7**
04	**10.7**	**4.8**	**6.4**	**2.0**
05	**10.2**	**4.9**	**17.5**	**37.5**
06	**4.1**	**4.1**	**3.8**	0.9
07	**3.9**	**2.7**	**3.4**	**1.1**
08	0.3	0.2	0.4	0.3
09	**10.6**	**4.6**	**8.0**	**4.1**
10	**20.5**	**8.4**	**12.3**	**9.5**
11	**36.5**	**15.5**	**14.3**	**50.1**
12	**34.1**	**7.6**	**17.5**	**193.0**
13	**23.6**	**12.6**	**9.6**	**1.8**
14	**127.5**	**50.3**	**18.8**	**41.9**
15	**127.9**	**41.9**	**17.8**	**108.0**
16	**116.7**	**55.1**	**17.9**	**24.0**
17	**41.6**	**16.9**	**15.6**	**5.6**
18	**58.6**	**6.7**	**14.3**	**13.2**
19	**23.5**	**6.0**	**17.9**	**291.3**
20	**13.7**	**3.4**	**7.9**	**39.9**
Test Date	29-Jul-09	05-Aug-09	03-Aug-09, 07-Aug-09	13-Aug-09
Test Site	RL	RL	RL	RL
Kit Part Code	4J27-20	7G46-48	GE42 (7G79-02)	4860446
Kit Lot No.	72331HN00	79496HN00	L283810	153019-01
Kit Exp. Date	14-Sep-09	28-Sep-09	31-Mar-10	31-Oct-09
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE	IVD/CE

[1]Results are reported as a signal to cutoff ratio (s/co); Ratios ≥1.0 are considered positive/reactive and noted in bold red.
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HIV Rapid Tests (s/co)[1]

Panel Member	Bio-Rad Multispot HIV-1/HIV-2		OraSure OraQuick ADVANCE® HIV-1/2 Result	Inverness Determine® HIV-1/2 Ag/Ab Combo	
	HIV-1 Result	HIV-2 Result		HIV Ag Result	HIV-1/2 Ab Result
01	NEG	NEG	NEG	**POS**	NEG
02	NEG	NEG	NEG	**POS**	**POS**
03	NEG	NEG	NEG	NEG	NEG
04	NEG	NEG	NEG	NEG	**POS**
05	NEG	NEG	NEG	NEG	**POS**
06	NEG	NEG	NEG	**POS**	NEG
07	NEG	NEG	NEG	NEG	NEG
08	NEG	NEG	NEG	NEG	NEG
09	NEG	NEG	NEG	NEG	**POS**
10	NEG	NEG	NEG	NEG	**POS**
11	NEG	NEG	**POS**	NEG	**POS**
12	**POS**	NEG	**POS**	NEG	**POS**
13	NEG	NEG	NEG	NEG	NEG
14	**POS**	NEG	NEG	**POS**	**POS**
15	**POS**	NEG	**POS**	NEG	**POS**
16	NEG	NEG	NEG	**POS**	**POS**
17	NEG	NEG	NEG	**POS**	**POS**
18	**POS**	NEG	**POS**	NEG	**POS**
19	**POS**	NEG	**POS**	NEG	**POS**
20	NEG	NEG	NEG	NEG	**POS**
Test Date	15 Dec 08, 12 Jun 09		15 Dec 08, 10 Feb 09	13 Aug 09, 24 Aug 09	
Test Site	SC		SC	SC	
Kit Part Code	25228		39-6341	2647	
Kit Lot No.	956768, 960383		6611458, 6612575	090216	
Kit Exp. Date	21 Jul 09, 20 Feb 10		31 Mar 09, 30 Jun 09	22 Nov 09	
Kit Regulatory Status	IVD		IVD	CE	

[1]Positive/reactive results are noted in bold red.
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HIV-1 Western Blot

	Calypte HIV-1 Western Blot	
Panel Member	**Band Pattern**	**Result[1,2]**
01	24	IND
02	No Bands	NEG
03	f24	IND
04	f24	IND
05	f24, 160	IND
06	f160	IND
07	No Bands	NEG
08	No Bands	NEG
09	f24, f160	IND
10	160	IND
11	f24, f120, 160	IND
12	24, f120, 160	**POS**
13	18	IND
14	18, f24, 160	IND
15	18, 24, 160	**POS**
16	f160	IND
17	f24, 160	IND
18	24, f41, f51, f120,160	**POS**
19	24, f41, f51, 55, 66, f120, 160	**POS**
20	24, f55, 160	**POS**
Test Date	29-May-09	
Test Site	SC	
Kit Part Code	98002	
Kit Lot No.	B9295-053	
Kit Exp. Date	22-Oct-09	
Kit Regulatory Status	IVD	

[1]Western Blots were interpreted using ASTPHLD/CDC criteria (MMWR, vol. 38, S-7, 1989).
[2]Positive/reactive results are noted in bold red.
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f = Faint; POS = Positive; IND= Indeterminate; NEG = Negative
IVD = In Vitro Diagnostic

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 info@seracare.com, or by phone at 508.244.6400.