

AccuSet™ Anti-HIV-1 Mixed Titer Performance Panel

PRB205(M3) / (0800-0379) / Batch # 10256270

OVERVIEW

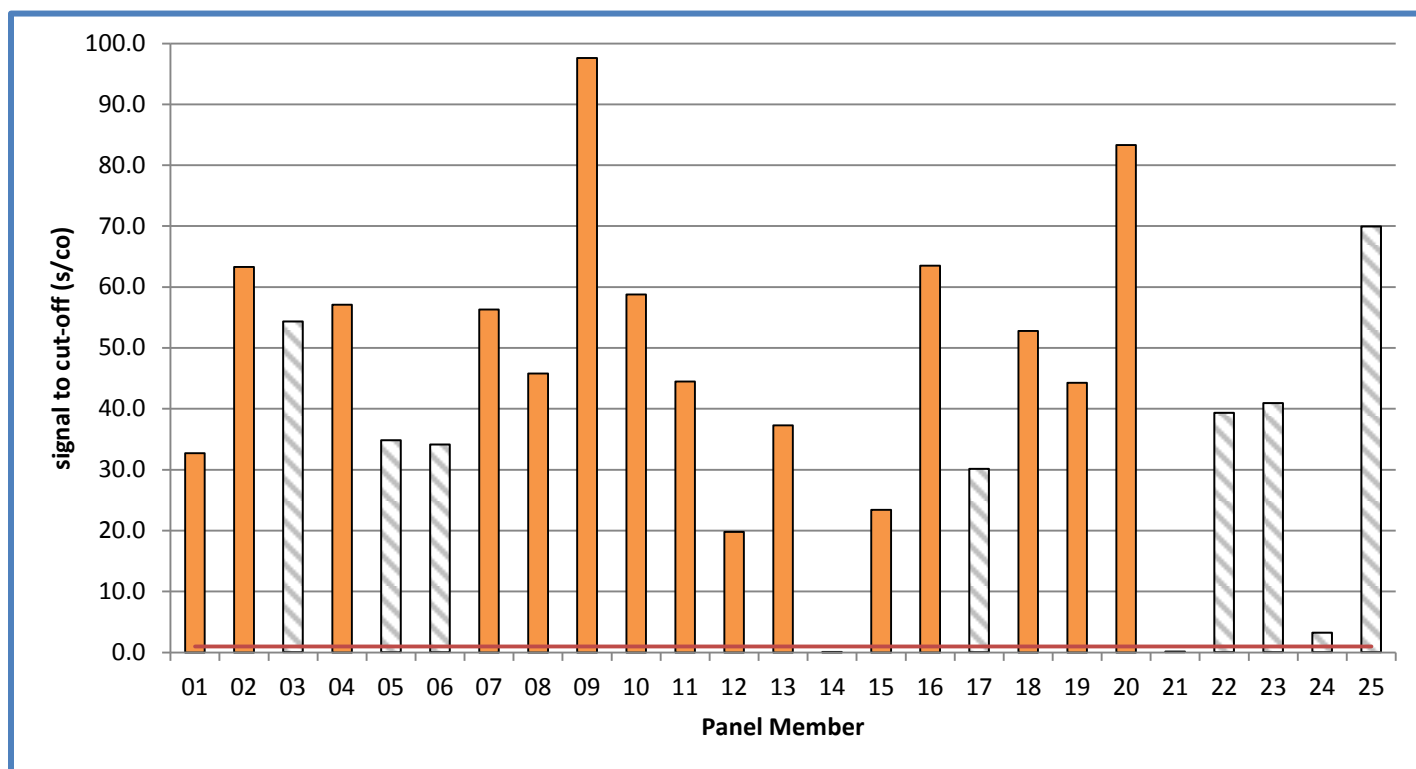
AccuSet™ Anti-HIV-1 Mixed Titer Performance Panel PRB205(M3) is a modified 16-member panel originating from Anti-HIV-1 Mixed Titer Performance Panel PRB205(M2). Panel members 3, 5, 6, 17, 21, 22, 23, 24, and 25 from the original panel are no longer available. Panel members are naturally-occurring plasma samples ranging from negative to strong positive for anti-HIV, with test results from 11 anti-HIV or antigen/antibody methods, including three rapid assays and two confirmatory methods. Fiebig stage and test results for HIV p24 antigen and HIV RNA are also included.

All members were processed by filtration through 0.8 µm filters. No preservatives were added.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for HIV Ag and/or anti-HIV-1; some were found positive for HBsAg (Member 2) and anti-HCV (Member 2 & 16).

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.

AccuSet™ Anti-HIV-1 Mixed Titer Performance Panel



This graph demonstrates anti-HIV reactivity amongst panel members utilizing test results from the Ortho HIV-1/HIV-2 VITROS ECi assay, members #3, 5, 6, 17, 21, 22, 23, 24, 25 are no longer available. Data is shown for informational purposes only.

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Panel Member Information

Panel Member	SeraCare Batch #	Fiebig Stage ¹
01	9182289	V
02	9116093	VI
03	ER9-1603-0004	III
04	BM217208	VI
05	9116072	VI
06	10000728	III
07	BM202269	III
08	9182331	IV
09	9119224	VI
10	9116120	V
11	10000612	VI
12	BM202285	III
13	9106103	VI
14	9127201	NA
15	9182332	V
16	9118527	VI
17	ER8-2710-0008	V
18	9231130	IV
19	9182411	VI
20	9126933	VI
21	9192330	NA
22	9121226	VI
23	10000546	V
24	BM202284	III
25	9230844	V

¹Fiebig 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.

*Panel members 3, 5, 6, 17, 21, 22, 23, 24 and 25 are no longer available and noted in grey; data are provided for informational purposes only.

NA = Not Available

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HIV RNA and HIV-1 Confirmatory

Panel Member	Roche HIV RNA CAP/CTM v1.0 (copies/mL)	Bio-Rad Western Blot Band Pattern	Bio-Rad Western Blot Result	Innogenetics INNO-LIA HIV I/II Band Pattern	Innogenetics INNO-LIA HIV I/II Result
01	1.2×10^3	24, f31, f51, 55, 160	POS	24, 41	POS
02	6.5×10^3	24, 31, 41, 51, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
03	5.7×10^4	No Bands	NEG	No Bands	NEG
04	1.4×10^6	f18, 24, 31, 41, 51, 55, 65, 120, 160	POS	24, 31, 41, 120	POS
05	4.4×10^3	18, 24, 31, 41, 51, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
06	2.3×10^3	No Bands	NEG	No Bands	NEG
07	1.1×10^5	No Bands	NEG	No Bands	NEG
08	2.9×10^7	18, 160	IND	41	IND
09	2.0×10^2	f18, 24, 31, 41, 51, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
10	7.0×10^3	18, 24, f31, 41, 51, 55, 65, 120, 160	POS	17, 24, 41, 120	POS
11	1.5×10^2	f18, 24, 31, 41, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
12	1.2×10^5	No Bands	NEG	No Bands	NEG
13	2.5×10^4	18, 24, 31, 41, 51, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
14	BLD	No Bands	NEG	No Bands	NEG
15	1.8×10^5	18, 24, f41, f51, 55, 65, 160	POS	17, 24, 41, 120	POS
16	4.6×10^4	18, 24, 31, 41, 51, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
17	1.5×10^4	f18, 24, f41, 51, 55, f65, f120, 160	POS	17, 24, 41, 120	POS
18	8.9×10^4	f160	IND	41	IND
19	6.2×10^2	18, 24, 31, f51, 55, f65, 160	POS	17, 24, 41, 120	POS
20	1.5×10^3	18, 24, 31, 41, 51, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
21	BLD	No Bands	NEG	No Bands	NEG
22	1.5×10^5	24, 31, 41, 51, 55, 65, 120, 160	POS	17, 24, 31, 41, 120	POS
23	BLD	f18, 24, 51, 55, 160	POS	17, 24, 41, 120	POS
24	1.5×10^5	No Bands	NEG	No Bands	NEG
25	BLD	f18, f24, 41, f51, 55, f65, 120, 160	POS	17, 24, 41, 120	POS
Test Date	18-May-10 19-May-10	02-Jul-10 08-Jul-10		20-Sep-10	
Test Site	SC	SC		RL	
Kit Part Code	M15645	32508		80540	
Kit Lot No.	3542998	967107		206153	
Kit Exp. Date	31-Jan-11	29-Dec-10		01-May-11	

BLD = Below the limit of detection; POS = Positive; NEG = Negative; IND = Indeterminate; f = Faint Band
RL = Reference Lab; SC = SeraCare

AccuSet™ Anti-HIV-1 Mixed Titer Performance Panel

PRB205(M3) / (0800-0379) / Batch # 10256270

HIV Antigen & HIV Antigen/Antibody (s/co)^{1,2}

Panel Member	Perkin Elmer HIV Ag p24	Abbott HIV Ag/Ab Combo ARCHITECT	Abbott HIV Ag/Ab Combo AxSYM	Abbott HIV Ag/Ab Combo PRISM	Bio-Rad Genscreen Ultra HIV Ag/Ab Combo	DiaSorin Murex HIV Ag/Ab Combo
01	0.4	16	8.5	3.1	>10.5	16.3
02	0.3	710.6	65.5	45.7	>10.5	18.8
03	>42.3	48.9	24	28.6	>10.5	16.0
04	0.5	645.9	49.9	43.2	>10.5	18.0
05	0.2	527.1	52.7	40.1	>10.5	17.1
06	1.6	2.2	3.2	1.8	8.2	4.2
07	7.6	7.3	12.1	5.2	>10.5	12.4
08	>42.3	489.3	73.9	158.1	>10.5	19
09	0.5	253.6	41.5	39.7	>10.5	16.9
10	0.3	440	40.1	36.1	>10.5	16.6
11	0.5	325.9	38.3	32.5	>10.5	18.6
12	10.7	12.9	7.8	6.7	4.6	8.1
13	0.3	210.1	17.2	15.5	>10.5	16.9
14	0.3	0.3	0.5	0.1	0.5	0.3
15	3.5	116.9	9.1	16.1	>10.5	15.6
16	0.4	285.9	53.7	33.3	>10.5	19.3
17	2.8	121.6	5.5	7.3	>10.5	16.6
18	3.6	11.8	9.3	4.9	>10.5	14.4
19	0.4	22.3	10.6	5.3	>10.5	16.2
20	0.3	606.7	76.6	38.5	>10.5	16.8
21	0.5	0.3	0.5	0.1	0.7	0.2
22	2.0	446.7	40.8	28	>10.5	15.5
23	0.4	181.2	14	13.8	>10.5	16.2
24	6.5	8.8	3.9	4.9	2.7	3.2
25	0.4	217.6	31.5	27.5	>10.5	17.4
Test Date	14-May-10	25-Aug-10	08-Sep-10	23-Aug-10	28-Sep-10	26-Aug-10 27-Aug-10
Test Site	SC	RL	RL	RL	SC	RL
Kit Part Code	NEK050B	4J27-30	2G8320	7G46-48	72386	7G79-09
Kit Lot No.	990-100306	89341HN00	89051LF01	91727HN00	OF1056	L377210
Kit Exp. Date	01-Nov-10	19-Jan-11	22-Oct-10	27-Jan-11	30-Nov-11	31-Jan-11

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

²Results are expressed as signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive and noted in bold red.

RL = Reference Lab; SC = SeraCare

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HIV Antibody (s/co)^{1,2}

Panel Member	Abbott HIV-1/HIV-2 rDNA	Avioq HIV-1 Microelisa System	Bio-Rad HIV-1rLAV Gen. Sys.	Bio-Rad HIV-1/HIV-2 Plus O Gen. Sys.	Ortho HIV-1/HIV-2 VITROS ECi	Siemens HIV-1/O/2 Enhanced ADVIA Centaur
01	7.2	3.6	3.7	>10.1	32.7	19.9
02	18.4	>7.5	9.5	>10.1	63.3	>50
03	15.7	0.8	1.1	>10.1	54.3	>50
04	>18.5	>7.5	9.5	>10.1	57.1	>50
05	>18.5	>7.5	9.7	>10.1	34.8	>50
06	6.7	1.8	0.4	>10.1	34.1	48.7
07	6.5	0.6	0.8	>10.1	56.3	>50
08	12.4	2.7	1.2	>10.1	45.8	19.2
09	>18.5	>7.5	9.2	>10.1	97.6	>50
10	>18.5	>7.5	9.6	>10.1	58.8	>50
11	>18.5	>7.5	9.5	>10.1	44.5	>50
12	6.9	0.4	0.5	2.5	19.8	16.6
13	>18.5	>7.5	8.5	>10.1	37.3	>50
14	0.2	0.2	0.1	0.4	0.1	0.6
15	10.8	5.5	4.5	>10.1	23.4	28.8
16	>18.5	>7.5	9.5	>10.1	63.5	>50
17	7.2	5.8	5.4	>10.1	30.1	>50
18	10.9	1.3	2.5	>10.1	52.8	>50
19	13.1	6.5	4.6	>10.1	44.3	>50
20	>18.5	>7.5	9.3	>10.1	83.3	>50
21	0.3	0.3	0.2	0.5	0.1	0.1
22	18.1	>7.5	9.4	>10.1	39.3	>50
23	15	7.2	6.4	>10.1	40.9	>50
24	1.2	0.2	0.1	0.2	3.2	1.9
25	>18.5	>7.5	8.2	>10.1	69.9	>50
Test Date	23-Aug-10	13-Sep-10	18-May-10	21-Sep-10	20-Aug-10	20-Sep-10 04-Aug-10
Test Site	SC	SC	SC	SC	RL	RL
Kit Part Code	3A77-68	100384	32511	32588	SP6801861	1622429
Kit Lot No.	85216M600	J0904	197DAA-05	104EBB-05	330	57278068
Kit Exp. Date	03-Nov-10	12-Jan-11	01-Jun-10	08-Dec-10	25-Jan-11	25-Dec-10

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

²Results are expressed as signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive and noted in bold red.

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HIV-1 Confirmatory

Panel Member	Bio-Rad Multispot HIV-1 Result	Bio-Rad Multispot HIV-2 Result	OraSure OraQuick Advance HIV-1/2 Result	Inverness Determine Combo HIV Ag Result	Inverness Determine Combo HIV Ab Result
01	POS	NEG	NEG	NEG	POS
02	POS	NEG	POS	NEG	POS
03	POS	NEG	NEG	POS	POS
04	POS	NEG	POS	NEG	POS
05	POS	NEG	POS	NEG	POS
06	POS	NEG	NEG	NEG	POS
07	NEG	NEG	NEG	POS	POS
08	NEG	NEG	NEG	POS	POS
09	POS	NEG	POS	NEG	POS
10	POS	NEG	POS	NEG	POS
11	POS	NEG	POS	NEG	POS
12	NEG	NEG	NEG	NEG	NEG
13	POS	NEG	POS	NEG	POS
14	NEG	NEG	NEG	NEG	NEG
15	POS	NEG	POS	NEG	POS
16	POS	NEG	POS	NEG	POS
17	POS	NEG	POS	NEG	POS
18	POS	NEG	NEG	NEG	POS
19	POS	NEG	POS	NEG	POS
20	POS	NEG	POS	NEG	POS
21	NEG	NEG	NEG	NEG	NEG
22	POS	NEG	POS	NEG	POS
23	POS	NEG	POS	NEG	POS
24	NEG	NEG	NEG	NEG	NEG
25	POS	NEG	POS	NEG	POS
Test Date	07-Sep-10		24-Sep-10		09-Sep-10
Test Site	SC		SC		SC
Kit Part Code	25228		6621583		7D26-46
Kit Lot No.	100590		1001.0079		100203
Kit Exp. Date	02-Feb-11		11-Nov-11		04-Dec-10

POS = Positive; NEG = Negative; SC = SeraCare

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