

AccuSet™ HIV-1 Low Titer Performance Panel

0800-0457 / Batch 10447001

OVERVIEW

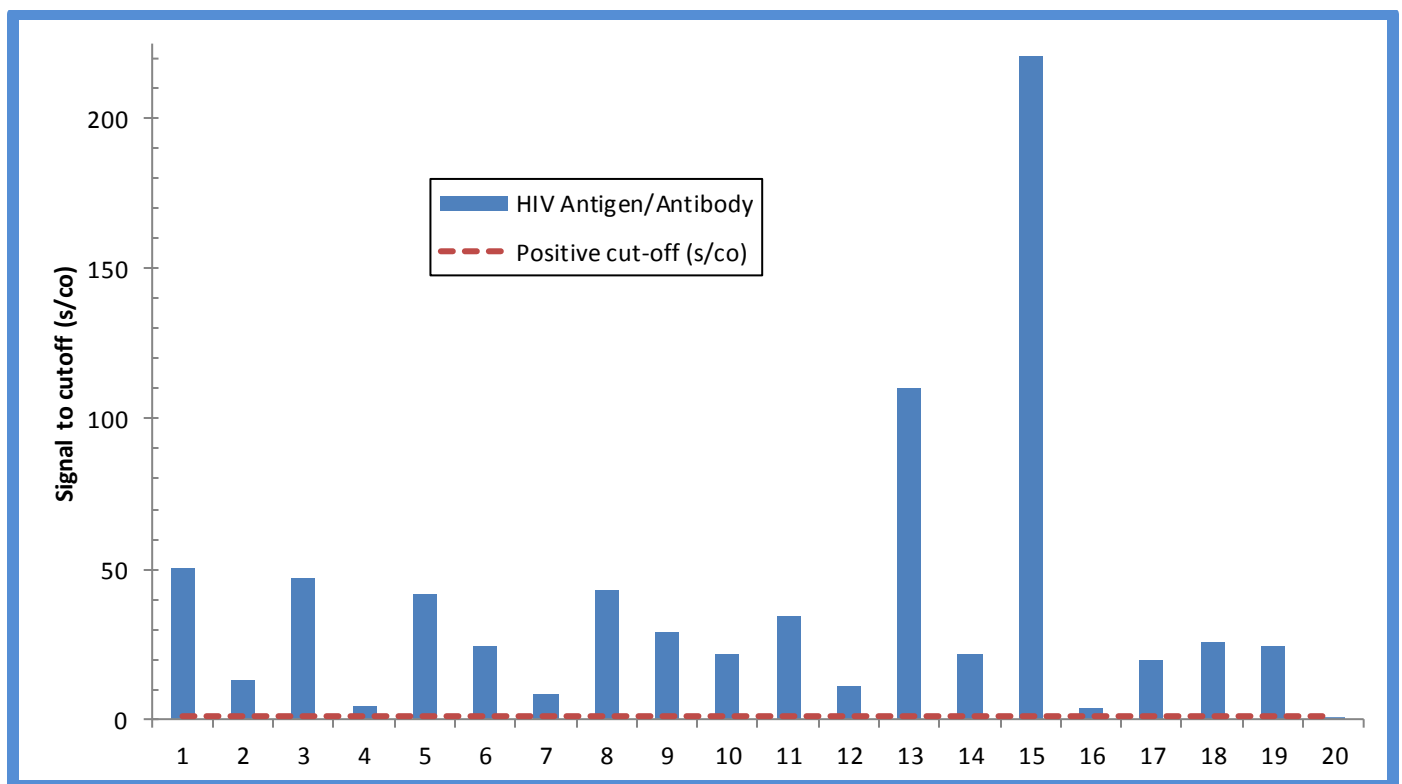
AccuSet™ HIV-1 Low Titer Performance Panel (0800-0457) is a 20-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HIV. Each sample represents a single collection event. No preservatives were added.

Test results from commercially available HIV assays are included for characterization of the panel members. 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 offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for HIV; all were found negative for anti-HCV and HBsAg. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates relative HIV antigen/antibody levels amongst panel members from the Abbott ARCHITECT HIV Ag/Ab test method (Positive cutoff: 1.0 s/co).

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	BM206262	BD102726	8-JUN-2006
02	10266905	BD328458	29-APR-2016
03	10418760	BD406213	27-DEC-2018
04	10266896	BD328454	26-JUL-2016
05	10401945	BD398598	12-SEP-2018
06	10418765	BD406216	7-DEC-2018
07	10418769	BD406219	9-NOV-2018
08	10418770	BD406220	2-NOV-2018
09	10418771	BD406220	31-OCT-2018
10	10430525	BD407032	21-MAR-2019
11	10430527	BD407034	25-OCT-2018
12	10430530	BD407033	14-FEB-2019
13	9222531	BD105878	20-DEC-2007
14	9230846	BD106689	29-APR-2008
15	BM202261	NA	18-JAN-2002
16	BM202272	NA	31-MAY-2002
17	BM206239	BD102670	22-MAY-2006
18	BM206240	BD102670	24-MAY-2006
19	BM217811	BD105709	14-SEP-2007
20	9178194	NA	31-JUL-2003

NA = Not Available

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HIV RNA and Antigen

Panel Member	Roche cobas® HIV-1 cobas® 6800 (cp/mL) ^{1,3}	Perkin Elmer HIV-1 p24 ELISA (s/co) ^{2,3}
01	6,005	1.3
02	560,500	7.6
03	7,855,000	42.5
04	1,264	0.6
05	43,000	0.5
06	13,850	0.2
07	159,000	0.6
08	24,100	0.2
09	24,850	0.3
10	127,500	1.4
11	67,450	0.2
12	24,200	0.4
13	2,040,000	69.0⁴
14	53,150	0.5
15	1,940,000	69.0⁴
16	8,070	3.5
17	17,600	3.5
18	56,050	7.5
19	634,000	18.9
20	TND	0.9
Test Date	15-NOV-2019	13-NOV-2019
Test Site	RL	SC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-19403
Kit Exp. Date	NA	01-AUG-2020

¹Results are reported as copies per milliliter (cp/mL); the conversion factor is 0.6 cp/IU; positive/reactive results are noted in bold red.

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

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

⁴Result is off scale.

NA = Not Available, TND = Target Not Detected, SC = SeraCare, RL = Reference Lab

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HIV Antigen / Antibody

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) ^{1,4}	Siemens ADVIA Centaur® HIV Ag/Ab Combo (Index) ^{2,4}	Ortho VITROS® HIV Combo (s/co) ^{1,4}	DiaSorin LIAISON® XL Murex HIV Ag/Ab (s/co) ^{1,4,5}	bioMérieux VIDAS® HIV Ag/Ab (TV) ^{3,4,5}
01	50.3	2.4	9.3	0.7 14.6	ND 2.0
02	13.2	11.8, >12.0⁶	21.8	3.7 9.5	1.9 ND
03	47.3	>12.0⁶	54.9	38.4 27.9	7.0 ND
04	4.6	2.1	6.1	0.4 5.9	0.0, ND 0.4
05	41.7	5.1	15.4	0.5 31.9	ND 5.8
06	24.1	4.4	13.0	0.4 29.8	ND 6.9
07	8.6	8.0	25.1	0.7 31.8	0.1 1.0
08	42.8	4.2	9.2	0.5 33.4	ND 2.2
09	28.8	4.9	9.0	0.5 30.3	0.1, ND 1.7
10	21.5	>12.0⁶	40.0	0.98 ⁷ 59.2	ND 2.4
11	34.4	4.2	15.8	0.4 47.0	ND 4.3
12	11.0	6.0	23.0	0.5 23.5	0.1 1.2
13	110.1	>12.0⁶	276.5	87.9 22.6	ND 7.7
14	21.9	>12.0⁶	15.0	0.5 68.2	ND 7.7
15	221.1	>12.0⁶	537.0	172.5 0.8	ND 9.1
16	3.6	3.9	17.5	1.6 3.4	1.1 0.3
17	19.6	11.1	14.0	1.8 23.5	ND 4.9
18	25.8	10.9	18.7	3.4 16.5	ND 2.6
19	24.1	>12.0⁶	47.5	14.0 0.8	7.0 ND
20	0.6	0.1	0.1	0.4 0.4	ND 0.1
Test Date	12-NOV-2019	19-NOV-2019	26-NOV-2019	18-NOV-2019	02-DEC-2019
Test Site	SC	RL	RL	RL	RL
Kit Part Code	2P36	NA	NA	310260	NA
Kit Lot No.	07190BE00	117215	0057	139040B	107311060
Kit Exp. Date	19-MAY-2020	14-APR-2020	13-JUL-2020	08-JUL-2020	22-APR-2020

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

²Results are reported as an Index; positive/reactive results are noted in bold red.

³Results are reported as Test Value; positive/reactive results are noted in bold red.

⁴Results are reported as the mean result of duplicate testing, except when individual results are presented.

⁵First value is antigen response; the second value is antibody response.

⁶Result is off scale.

⁷The assay cutoff is 1.000.

ND = Not Determinable; NA = Not Available, SC = SeraCare; RL = Reference Lab

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HIV Antibody

Panel Member	Bio-Rad Genetic Systems™ HIV-1 / HIV-2 Plus O EIA (s/co) ^{1,2}	Avioq HIV-1 Microelisa (s/co) ^{1,2}	OraSure OraQuick® HIV Rapid Antibody Test ⁴
01	12.5 ³	4.0	POS
02	12.5 ³	5.3	POS
03	12.5 ³	5.2	POS
04	10.6	2.1	POS
05	12.5 ³	6.6	POS
06	12.5 ³	7.0	POS
07	12.5 ³	6.4	POS
08	12.5 ³	5.9	POS
09	12.5 ³	4.5	POS
10	12.5 ³	3.4	POS
11	12.5 ³	8.1	POS
12	12.5 ³	5.8	POS
13	12.5 ³	0.8	NEG
14	12.5 ³	5.2	POS
15	12.5 ³	0.3	NEG
16	0.98; 1.1 ⁵	0.4	POS
17	12.5 ³	0.6	POS
18	12.5 ³	1.1	POS
19	0.2	0.3	NEG
20	0.1	0.2	NEG
Test Date	13-NOV-2019	14-NOV-2019	13-NOV-2019
Test Site	SC	SC	SC
Kit Part Code	32588	100384	1001.0079
Kit Lot No.	123PBB-05	18105H	0006672847
Kit Exp. Date	31-Jan-2020	11-JUN-2020	30-NOV-2021

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, except when individual results are presented.

³Result is off-scale.

⁴Positive/reactive results are noted in bold red.

⁵The assay cutoff is 1.000.

SC = SeraCare; POS = Positive; NEG = Negative

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Anti-HIV Confirmatory

Panel Member	Bio-Rad GS HIV-1 Western Blot		Innogenetics INNO-LIA™ HIV I/II Score	
	Band Pattern	Result ¹	Band Pattern	Result ¹
01	f18, 24, f55, f160	IND	f17, 24, 41, 120	HIV-1 POS
02	24, f65, f160	IND	24, 41	HIV-1 POS
03	24, f55, f160	IND	24, 41	HIV-1 POS
04	24, 55, f160	IND	17, 24, 41, 120	HIV-1 POS
05	24, 31, 55, f65, 160	POS	17, 24, 31, 41	HIV-1 POS
06	18, 24, 55, 160	POS	17, 24, 41	HIV-1 POS
07	24, f31, 55, 160	POS	17, 24, 41	HIV-1 POS
08	24, 55, 160	POS	17, 24, 41, 120	HIV-1 POS
09	24, 55, 160	POS	17, 24, 41, 120	HIV-1 POS
10	24, f55, 160	POS	24, 41	HIV-1 POS
11	24, f31, 55, 65, 160	POS	24, 41	HIV-1 POS
12	f18, 24, 55, 160	POS	f17, 24, 41	HIV-1 POS
13	–	NEG	f41	NEG
14	24, f31, 55, 65, 160	POS	17, 24, 41, 120	HIV-1 POS
15	–	NEG	f41	NEG
16	–	NEG	–	NEG
17	–	NEG	41	IND
18	–	NEG	41	IND
19	18	IND	–	NEG
20	–	NEG	–	NEG
Test Date	20-NOV-2019; 21-NOV-2019		04-DEC-2019	
Test Site	SC		RL	
Kit Part Code	32508		NA	
Kit Lot No.	64250342		406154	
Kit Exp. Date	28-MAR-2020		31-MAY-2020	

¹ Positive/reactive results are noted in bold red.

f = Faint band; POS = Positive; NEG = Negative; IND = Indeterminant; SC = SeraCare; RL = Reference Lab; NA = Not Available

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.