

AccuSet™ HIV-1/2 Performance Panel

0800-0380 / Batch # 10311987

OVERVIEW

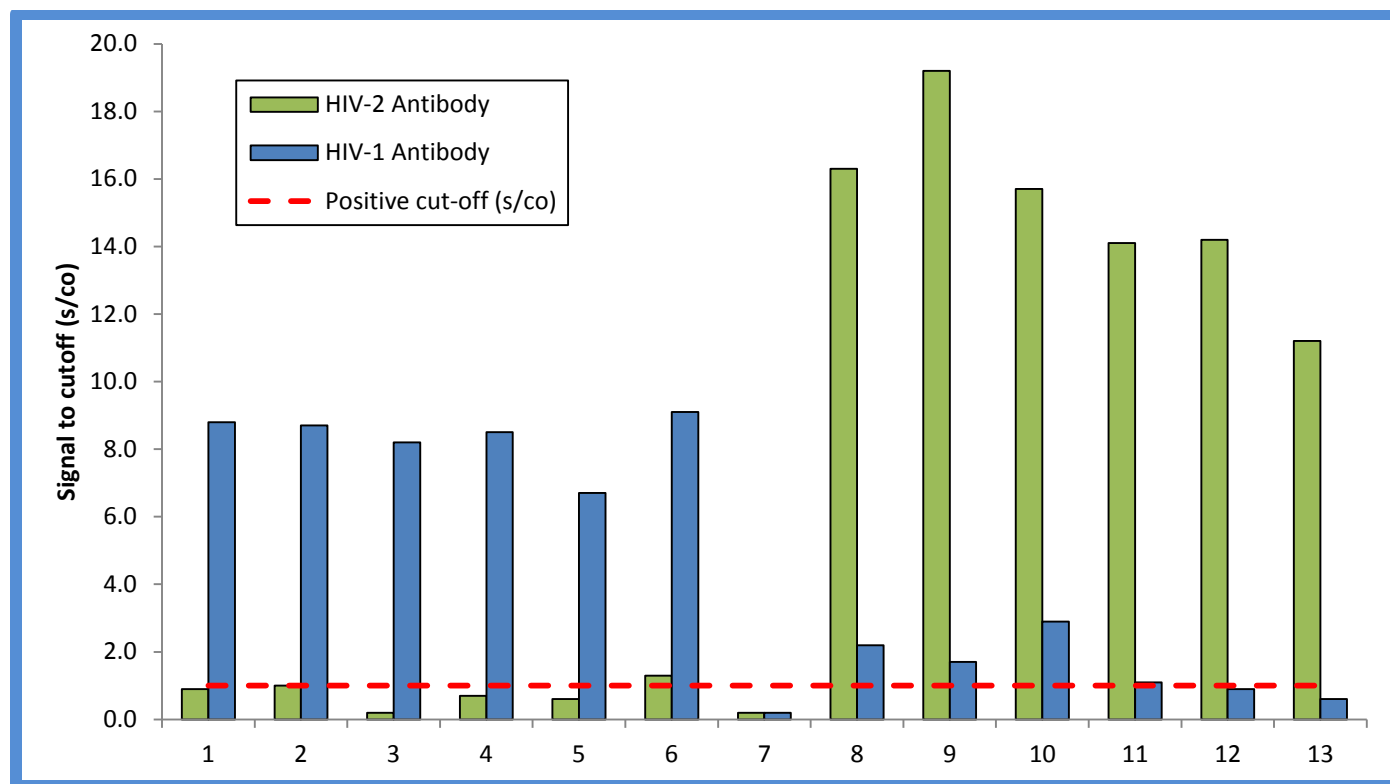
AccuSet™ HIV-1/2 Performance Panel (0800-0380) is a 13-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HIV-1/2. Each sample represents a single collection 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 for several anti-HIV-1/2 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.

AccuSet™ HIV-1/2 Performance Panel



This graph demonstrates reactivity amongst panel members using the Avioq HIV-1 Microelisa system and Bio-Rad Genetic Systems HIV-2 EIA test methods.

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Performance Panel
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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	BM206260	BD102725	19-Jun-2006
02	10000723	BD217616	9-Nov-1998
03	10000751	BD217613	7-Nov-1997
04	10112113	BD240183	15-Dec-2014
05	9103159	NA	NA
06	9145673	NA	NA
07	10310079	BD349121	05-Jun-2017
08	10266759	BD200052	17-Mar-2014
09	10043357	BD110613	24-Feb-2014
10	10058357	BD217635	5-Mar-2014
11	10096585	BD110417	12-Dec-2014
12	10101738	BD200481	21-Jan-2015
13	9228983	BD110378	29-Jan-2008

NA = Not Available

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HIV Antigen, HIV Ag/Ab Combo

Panel Member	Perkin Elmer Alliance HIV-1 p24 ELISA (s/co) ^{1,3}	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) ^{1,3}	Abbott PRISM HIV Ag/Ab Combo (s/co) ^{1,3}	Siemens ADVIA Centaur HIV Ag/Ab Combo (INDEX) ^{2,3}
01	0.1	1333.4	127.2	>12.00
02	0.3	1339.5	177.0	>12.00
03	0.4	756.8	86.6	>12.00
04	0.3	1368.5	164.1	>12.00
05	0.1	402.6	112.6	>12.00
06	0.2	575.3	130.3	>12.00
07	0.0 ^A	0.2 ^A	0.3 ^A	0.1 ^A
08	0.1	232.8	132.6	>12.00
09	0.1	285.0	122.2	8.7
10	0.2	191.9	106.8	>12.00
11	0.1	160.8	110.8	>12.00
12	0.1	161.4	113.4	>12.00
13	0.1	179.5	68.3	9.7
Test Date	05-Feb-2018 12-Apr-2018 ^A	05-Feb-2018 02-Apr-2018 ^A	06-Feb-2018 03-Apr-2018 ^A	08-Feb-2018 04-Apr-2018 ^A
Test Site	SC	SC	RL	RL
Kit Part Code	NEK 050A	2P36	NA	NA
Kit Lot No.	990-17441 990-18102 ^A	78020LI00 78484LI00 ^A	NA	50764138 78651140 ^A
Kit Exp. Date	01-Aug-2018 01-Nov-2018 ^A	01-Apr-2018 29-Apr-2018 ^A	NA	15-Jul-2018 06-Sep-2018 ^A
Kit Regulatory Status	RUO	IVD/CE	IVD/CE	IVD/CE

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

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

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

^A Negative member was not tested on the same run as HIV-1/2 positive members; information applies to negative member testing.

RL = Reference Lab; SC = SeraCare; NA = Not available

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

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HIV Rapid Tests ^{1,2}

Panel Member	Alere Determine HIV-1/2 Ag/Ab Combo HIV Ab Interpretation	Alere Determine HIV-1/2 Ag/Ab Combo HIV Ag Interpretation	OraSure OraQuick ADVANCE Rapid HIV-1/2 Antibody Test
01	POS	NEG	POS
02	POS	NEG	POS
03	POS	NEG	POS
04	POS	NEG	POS
05	POS	NEG	POS
06	POS	NEG	POS
07	NEG ^A	NEG ^A	NEG ^A
08	POS	NEG	POS
09	POS	NEG	POS
10	POS	NEG	POS
11	POS	NEG	POS
12	POS	NEG	POS
13	POS	NEG	POS
Test Date	12-Feb-2018 02-Apr-2018 ^A		12-Feb-2018 09-Apr-2018 ^A
Test Site	SC		SC
Kit Part Code	7D2648		1001.0079
Kit Lot No.	095424 161027 ^A		0006662071 0006661706 ^A
Kit Exp. Date	22-Jun-2019 05-Apr-2018 ^A		31-Mar-2020 31-Mar-2020 ^A
Kit Regulatory Status	IVD		IVD

¹Positive/reactive results are noted in bold red.

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HIV-1 Antibody / HIV-2 Antibody

Panel Member	Avioq HIV-1 Microelisa System (s/co) ^{1,2}	Bio-Rad Genetic Systems HIV-2 EIA (s/co) ^{1,2}	Trinity Biotech Uni-Gold Recombigen HIV-1/2 ²
01	8.8	0.9	POS
02	8.7	1.0	POS
03	8.2	0.2	POS
04	8.5	0.7	POS
05	6.7	0.6	POS
06	9.1	1.3	POS
07	0.2 ^A	0.2 ^A	NEG ^A
08	2.2	16.3	POS
09	1.7	19.2	POS
10	2.9	15.7	POS
11	1.1	14.1	POS
12	0.9	14.2	POS
13	0.6	11.2	POS
Test Date	06-Feb-2018 12-Apr-2018 ^A	07-Feb-2018 06-Apr-2018 ^A	09-Feb-2018 09-Apr-2018 ^A
Test Site	SC	SC	SC
Kit Part Code	100384	32536	1206506
Kit Lot No.	17120H 17125H ^A	123MY1-05	H205004
Kit Exp. Date	20-Oct-2018 09-Jul-2019 ^A	07-Apr-2018	06-Jul-2018
Kit Regulatory Status	IVD	IVD	IVD

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HIV-1/2 Confirmatory

Panel Member	Bio-Rad Geenius™ HIV 1/2 Confirmatory Assay Band Pattern	Bio-Rad Geenius™ HIV-1 Interpretation	Bio-Rad Geenius™ HIV-2 Interpretation
01	24, 31, 41, 140, 160	POS	IND
02	31, 41, 160	POS	NR
03	31, 41, 160	POS	NR
04	24, 31, 41, 160	POS	NR
05	41, 160	POS	NR
06	31, 41, 160	POS	NR
07	No bands ^A	NEG ^A	NEG ^A
08	31, 36, 41, 140, 160	R	POS
09	24, 36, 140	IND	POS
10	24, 31, 36, 41, 140	R	POS
11	31, 36, 140	IND	POS
12	31, 36, 140	IND	POS
13	36, 140	NR	POS
Test Date	06-Feb-2018 03-Apr-2018 ^A		
Test Site	RL		
Kit Part Code	NA		
Kit Lot No.	7D0023		
Kit Exp. Date	15-Mar-2019		
Kit Regulatory Status	IVD/CE		

¹Positive/reactive results are noted in bold red.

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POS = Positive; NEG = Negative; IND = Indeterminate; R = Reactive; NR = Non-reactive

RL = Reference Lab

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HIV-1 Confirmatory¹

Panel Member	Bio-Rad Genetic Systems HIV-1 Western Blot Band Pattern	Bio-Rad Genetic Systems HIV-1 Western Blot Interpretation
01	18, 24, 31, 41, 51, 55, 65/6, 120, 160	POS
02	31, 41, 55, 65/6, 120, 160	POS
03	31, 41, 51, 55, 65/6, 120, 160	POS
04	18, 24, 31, 41, 51, 55, 65/6, 120, 160	POS
05	18, 24, 51, 55, 65/6, 120, 160	POS
06	24, 31, 41, 55, 65/6, 120, 160	POS
07	No Bands ^A	NEG ^A
08	24, 31, 55	IND
09	24, 31, 55	IND
10	18, 24, 31, 41, 55, 65/6, 160	IND
11	24, 31, 55, 65/6, 160	IND
12	24, 31, 65/6	IND
13	24	IND
Test Date	06-Feb-2018 11-Apr-2018 ^A	
Test Site	SC	
Kit Part Code	32508	
Kit Lot No.	64101076 64134381 ^A	
Kit Exp. Date	31-May-2018 10-Oct-2018 ^A	
Kit Regulatory Status	IVD	

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HIV-1/2 Confirmatory¹

Panel Member	Fujirebio INNO-LIA HIV-I/II Score Band Pattern	Fujirebio INNO-LIA HIV-I Interpretation	Fujirebio INNO-LIA HIV-II Interpretation
01	17, 24, 31, 41, 120	POS	NEG
02	17, 24, 31, 41, 120	POS	NEG
03	24, 31, 41, 120	POS	NEG
04	17, 24, 31, 41, 120	POS	NEG
05	17, 24, 41, 120	POS	NEG
06	17, 24, 31, 41, 120	POS	NEG
07	No Bands ^A	NEG ^A	NEG ^A
08	17, 24, 31, 36, 105	NEG	POS
09	24, 31, 36, 105	NEG	POS
10	17, 24, 31, 36, 105	NEG	POS
11	17, 24, 31, 36, 105	NEG	POS
12	17, 24, 31, 36, 105	NEG	POS
13	24, 36, 105	NEG	POS
Test Date	26-Feb-2018 17-Apr-2018 ^A		
Test Site	RL		
Kit Part Code	NA		
Kit Lot No.	404749		
Kit Exp. Date	31-Aug-2019		
Kit Regulatory Status	IVD/CE		

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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 info@seracare.com or by phone at 508.244.6400.