AccuSet™ HIV-1/2 Performance Panel

0800-0380 / Batch # 10311987

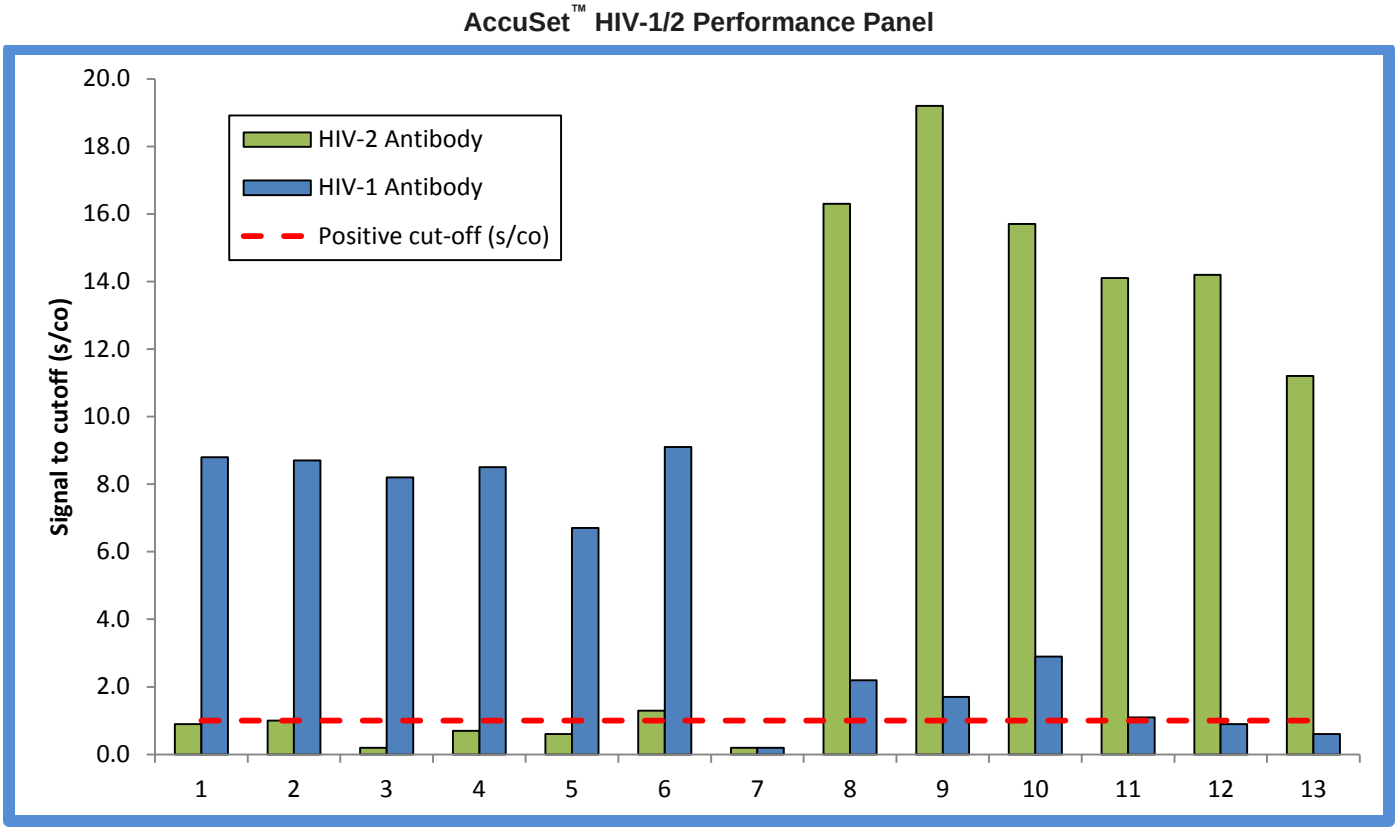
OVERVIEW

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.



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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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

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

[1]Positive/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

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

[1]Positive/reactive results are noted in bold red.

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

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HIV-1 Confirmatory[1]

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 Confirmatory[1]

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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