AccuSet™ HIV-1 Early Infection Performance Panel

0800-0394 / Batch #10438828

OVERVIEW

AccuSet™ HIV-1 Early Infection Performance Panel 0800-0394 / Batch #10438828 is a 25-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from individuals positive for HIV-1 at varying Fiebig stages for HIV-1 primary infection (Eclipse, I, II, III, IV, V). Each member represents a single collection event, and in most cases, serial bleeds from the same individual are provided in the panel (see page 3 for donor ID information). No preservatives were added.

Test results from commercially available HIV assays are included for characterization of the panel members, including HIV-1 RNA, antigen/antibody, p24 antigen, western blot, and confirmatory test methods.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. LGC/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 HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.

AccuSet™ HIV-1 Early Infection Performance Panel[1,2]

Fiebig Stage and Defined Finding	Duration of each Phase (days)	Cumulative Duration (days)
Eclipse	10 (7 - 21)	10 (7 - 21)
I (Viral RNA+)	7 (5 - 10)	17 (13 - 28)
II (p24 Antigen+)	5 (4 - 8)	22 (18 - 34)
III (Antibody ELISA+)	3 (2 - 5)	25 (22 - 37)
IV (Western Blot +/-)	6 (4 - 8)	31 (27 - 43)
V (Western Blot +, p31-)	70 (40 - 122)	101 (71 - 154)
VI (Western Blot +, p31+)	Open-ended	

1 *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, 17:1871–1879.*

2 *Cohen MS, et al. The Detection of Acute HIV Infection. J Infect Dis 2010, 202 (Suppl 2):S270-S277. Figure adapted from Table 1. Fiebig Stage Classifications for Substages of Human Immunodeficiency Virus Type 1 Primary Infection, with Durations.*

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Panel Member Information by Fiebig Stage (Eclipse – V)

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Fiebig Stage
01	9241475	BD110025	29-Jun-2009	Eclipse
02	10000656	BD226035	27-Oct-1997	I
03	9254201	BD110974	17-Jul-2010	Eclipse
04	10418761	BD406214	08-Nov-2018	Eclipse
05	9106274	NA	19-Apr-1999	I
06	10000657	BD226035	29-Oct-1997	I
07	BM216453	BD102986	31-May-2006	I
08	10266923	BD328464	01-Oct-2015	I
09	9241477	BD110025	08-Jul-2009	I
10	9254199	BD110974	24-Jul-2010	I
11	10000672	BD226038	17-Dec-1996	I
12	9106275	NA	21-Apr-1999	II
13	10000658	BD226035	04-Nov-1997	II
14	9241479	BD110026	03-Jul-2009	II
15	9254202	BD110974	29-Jul-2019	II
16	10266892	BD328452	18-May-2016	V
17	10000675	BD226038	06-Jan-1997	IV
18	9251693	BD111065	31-May-2002	IV
19	10418762	BD406214	03-Dec-2018	IV
20	10418763	BD406214	05-Dec-2018	IV
21	BM216457	BD102986	14-Jun-2006	IV
22	10266924	BD328464	30-Oct-2015	V
23	BM216458	BD102986	21-Jun-2006	V
24	10418767	BD406218	27-Nov-2018	V
25	10418768	BD406218	29-Nov-2018	V

NA = Not Available

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Panel Member Information by Donor ID (Multi / Single Bleed)

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Fiebig Stage
7	BM216453	BD102986	31-May-2006	I
21	BM216457	BD102986	14-Jun-2006	IV
23	BM216458	BD102986	21-Jun-2006	V
1	9241475	BD110025	29-Jun-2009	Eclipse
9	9241477	BD110025	08-Jul-2009	I
14	9241479	BD110026	03-Jul-2009	II
3	9254201	BD110974	17-Jul-2010	Eclipse
10	9254199	BD110974	24-Jul-2010	I
15	9254202	BD110974	29-Jul-2019	II
18	9251693	BD111065	31-May-2002	IV
2	10000656	BD226035	27-Oct-1997	I
6	10000657	BD226035	29-Oct-1997	I
13	10000658	BD226035	04-Nov-1997	II
11	10000672	BD226038	17-Dec-1996	I
17	10000675	BD226038	06-Jan-1997	IV
16	10266892	BD328452	18-May-2016	V
8	10266923	BD328464	01-Oct-2015	I
22	10266924	BD328464	30-Oct-2015	V
4	10418761	BD406214	08-Nov-2018	Eclipse
19	10418762	BD406214	03-Dec-2018	IV
20	10418763	BD406214	05-Dec-2018	IV
24	10418767	BD406218	27-Nov-2018	V
25	10418768	BD406218	29-Nov-2018	V
5	9106274	NA	19-Apr-1999	I
12	9106275	NA	21-Apr-1999	II

NA = Not Available

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HIV-1 RNA, HIV Ag/Ab[1]

Panel Member	Roche cobas® 6800/8800 HIV-1 (copies/mL)	Abbott ARCHITECT HIV Ag/Ab Combo (s/co)	Ortho VITROS® HIV Combo (s/co)	Roche Elecsys HIV combi PT (s/co)	Siemens ADVIA Centaur® HIV Ag/Ab Combo (Index)
01	TND	0.12	0.1	0.2	0.2
02	**<20, 57***	0.13	0.1	0.2	0.2
03	TND	0.20	0.1	0.2	0.2
04	TND	0.24	0.1	0.2	0.1
05	**1.31×10^4**	0.20	0.1	0.7	0.2
06	**6.45×10^2**	0.15	0.1	0.2	0.2
07	**2.69×10^3**	0.18	0.1	0.2	0.2
08	**3.25×10^4**	0.43	0.2	0.4	0.3
09	**5.61×10^4**	0.72	0.4	0.6	0.5
10	**2.87×10^3**	0.21	0.1	0.2	0.2
11	**1.78×10^3**	0.31	0.2	0.2	0.3
12	**1.57×10^5**	**1.19**	0.4	**1.4**	0.8
13	**6.99×10^5**	**15.87**	**24.0**	**8.6**	**7.9**
14	**4.24×10^5**	**6.48**	**8.0**	**3.6**	**3.3**
15	**9.37×10^5**	**24.12**	**24.9**	**11.7**	**9.3**
16	**4.83×10^6**	**271.87**	**38.1**	**181.3**	**>12.0**
17	**2.55×10^3**	**10.07**	**10.1**	**58.9**	**5.7**
18	**9.24×10^3**	**5.34**	**16.5**	**2.6**	**7.1**
19	**$>1.00 \times 10^7$**	**197.92**	**148.5**	**297.3**	**>12.0**
20	**9.28×10^6 $>1.00 \times 10^7$***	**101.72**	**69.7**	**215.6**	**>12.0**
21	**4.71×10^5**	**43.33**	**30.5**	**65.2**	**>12.0**
22	**4.74×10^5**	**67.96**	**15.8**	**303.3**	**6.3**
23	**1.60×10^5**	**39.56**	**12.6**	**100.8**	**>12.0**
24	**1.46×10^3**	**238.82**	**38.6**	**99.1**	**>12.0**
25	**1.52×10^3**	**152.98**	**29.8**	**97.6**	**11.1**
Test Date	25-Mar-2024	22-Mar-2024	20-Aug-2019	27-Aug-2019	20-Aug-2019
Test Site	RL	SC	RL	RL	RL
Kit Part Code	NA	2P36	NA	NA	NA
Kit Lot No.	NA	59215BE00	0090	NA	210
Kit Exp. Date	NA	13-Aug-2024	07-Apr-2020	NA	22-Feb-2020

[1]Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.
*Individual replicates reported, mean could not be determined.
RL = Reference Lab; SC = SeraCare; NA = Not Available; TND = Target Not Detected

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HIV-1 Ag, HIV-1/2 Ab

Panel Member	Perkin Elmer HIV-1 p24 ELISA (s/co)[1]	Abbott PRISM HIV O Plus (s/co)[1]	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA (s/co)[1]	Avioq HIV-1 Microelisa System (s/co)[1]	OraSure OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test[2]
01	0.18	0.3	0.12	0.22	NEG
02	0.17	0.3	0.12	0.26	NEG
03	0.22	0.3	0.18	0.23	NEG
04	0.22	0.3	0.18	0.24	NEG
05	0.36	0.4	0.11	0.24	NEG
06	0.21	0.3	0.09	0.25	NEG
07	0.32	0.3	0.16	0.24	NEG
08	0.69	0.3	0.17	0.22	NEG
09	0.97	**23.0**	0.14	0.23	NEG
10	0.30	0.3	0.12	0.23	NEG
11	0.47	0.3	0.17	0.27	NEG
12	**1.75**	0.3	0.19	0.23	NEG
13	**17.31**	0.3	0.10	0.25	NEG
14	**8.70**	0.3	0.14	0.21	NEG
15	**23.47**	0.3	0.13	0.22	NEG
16	**39.91**	**16.6**	**>13.61**	**3.42**	**POS**
17	0.25	**31.8**	**>13.61**	**2.38**	**POS**
18	**1.89**	**1.8**	**>13.61**	**1.21**, 0.93*	**POS**
19	**>68.97**	**14.6**	**>13.61**	**3.45**	**POS**
20	**58.67**	**18.7**	**>13.61**	**3.86**	**POS**
21	**4.93**	**26.1**	**>13.61**	**2.46**	**POS**
22	**1.75**	**44.4**	**>13.61**	**6.60**	**POS**
23	**1.59**	**26.3**	**>13.61**	**3.33**	**POS**
24	0.17	**20.8**	**>13.61**	**4.82**	**POS**
25	0.15	**18.8**	**>13.61**	**5.72**	**POS**
Test Date	22-Mar-2024	21-Aug-2019	22-Mar-2024	22-Mar-2024	21-Aug-2019
Test Site	SC	RL	SC	SC	SC
Kit Part Code	NEK050A	NA	32588	100384	1001.0079
Kit Lot No.	990-23485	02009N100	312UBB-05	23106H	0006672305, 0006668721, 0006670912
Kit Exp. Date	01-Sep-2024	27-Nov-2019	30-Sep-2024	02-Dec-2024	31-Oct-2021, 31-Jan-2021, 31-Jul-2021

[1]Results are reported as the mean result of duplicate testing ; positive/reactive results are noted in bold red.
[2]Results are reported as singlicate testing; positive/reactive results are noted in bold red.
*Individual replicates reported, interpretation variability.
POS = Positive; NEG = Negative; RL = Reference Lab; SC = SeraCare; NA = Not Available

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HIV-1 Western Blot, HIV-1 Confirmatory[1]

Panel Member	Fujirebio INNO-LIA™ HIV-I/II Score Band Pattern	Fujirebio INNO-LIA™ HIV-I/II Score Result	Bio-Rad Genetic Systems™ HIV-1 Western Blot Band Pattern	Bio-Rad Genetic Systems™ HIV-1 Western Blot Result
01	No Bands	NEG	No Bands	NEG
02	No Bands	NEG	f24	IND
03	No Bands	NEG	No Bands	NEG
04	No Bands	NEG	No Bands	NEG
05	No Bands	NEG	55	IND
06	No Bands	NEG	f24	IND
07	No Bands	NEG	No Bands	NEG
08	No Bands	NEG	No Bands	NEG
09	No Bands	NEG	No Bands	NEG
10	No Bands	NEG	No Bands	NEG
11	No Bands	NEG	f18	IND
12	No Bands	NEG	55	IND
13	No Bands	NEG	f18, f24	IND
14	No Bands	NEG	No Bands	NEG
15	No Bands	NEG	No Bands	NEG
16	**24, 41, 120**	**POS**	**24, f55, 160**	**POS**
17	**17, 24, 41**	**POS**	f18, 24, 55, f160	IND
18	**17, 24, 41**	**POS**	24	IND
19	**17, 24, 41**	**POS**	18, 24, f55, f160	IND
20	**17, 24, 41**	**POS**	18, 24, f55, f160	IND
21	41	IND	f18, f24, f160	IND
22	**17, 24, 41, 120**	**POS**	**18, 24, 55, f120, 160**	**POS**
23	**17, 24, 41**	**POS**	**f18, 24, f55, 160**	**POS**
24	**17, 24, 41**	**POS**	**18, 24, f31, f41, 55, 160**	**POS**
25	**17, 24, 41**	**POS**	**18, 24, f31, f41, 55, 160**	**POS**
Test Date	03-Sep-2019		27-Aug-2019	
Test Site	RL		SC	
Kit Part Code	NA		32508	
Kit Lot No.	405890		64203868	
Kit Exp. Date	31-Mar-2020		02-Nov-2019	

[1]Results are reported as singlicate testing; positive/reactive results are noted in bold red.
POS = Positive, IND = Indeterminate, NEG = Negative; RL = Reference Lab, SC = SeraCare; NA = Not Available
f = Faint band

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 CDx-Info@LGCGroup.com or by phone at 508.244.6400.