

OVERVIEW

HIV-1 Early Infection AccuSet™ Performance Panel (0800-0297) is a 23-member panel of undiluted, naturally occurring plasma samples. Panel members represent bleeds from several individuals positive for HIV-1 of varying Fiebig stages for HIV-1 primary infection (Eclipse, I, II, III, IV, and V). Several donor collection sets within this panel demonstrate disease progression over the course of time. 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, including HIV-1 RNA, p24 antigen, antibody, antigen/antibody, western blot, and confirmatory test methods.

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. All panel members were found negative for HBsAg and anti-HCV.

Fiebig Classification for HIV-1 Primary Infection^{1,2}

Fiebig Stage and Defined Finding	Duration Individual phase (days) Mean (range)	Duration Cumulative (days) Mean (range)
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 + or -)	6 (4 - 8)	31 (27 - 43)
V (Western Blot +, p31 -)	70 (40 - 122)	101 (71 - 154)
VI (Western Blot +, p31 +)	Open-ended	

References:

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 Members by Fiebig Stage (Eclipse – V)

Panel Member ¹	Donor ID	Bleed Date	Fiebig Stage
01	BD106705	3/31/2008	Eclipse
02	BD110025	6/29/2009	Eclipse
03	BD110974	7/17/2010	Eclipse
04	BD110450	7/20/1999	Eclipse
05	BD106705	4/9/2008	I
06	BD110025	7/6/2009	I
07	BD110025	7/8/2009	I
08	BD110974	7/24/2010	I
09	BD110974	7/29/2010	II
10	BM202263	4/25/2002	II
11	BD110026	7/3/2009	II
12	BM202306	11/12/2002	II
13	BD110201	4/24/2010	III
14	ER8-2306-0001	1/22/1997	III
15	BD111091	8/13/2001	III
16	BM202277	6/8/2002	III
17	BD106705	4/25/2008	IV
18	BD105709	9/19/2007	IV
19	BD110038	9/8/1999	IV
20	BD111065	5/31/2002	IV
21	BD110201	4/29/2010	V
22	BD105709	9/21/2007	V
23	BD110038	9/22/1999	V

¹Panel members 10, 12, 14, and 16 are identified by SeraCare batch #.

Panel Members by Donor ID (Multi /Single Bleed)

Donor ID	Panel Member ¹	Bleed Date	Fiebig Stage
BD105709	18	9/19/2007	IV
BD105709	22	9/21/2007	V
BD106705	1	3/31/2008	Eclipse
BD106705	5	4/9/2008	I
BD106705	17	4/25/2008	IV
BD110025	2	6/29/2009	Eclipse
BD110025	6	7/6/2009	I
BD110025	7	7/8/2009	I
BD110038	19	9/8/1999	IV
BD110038	23	9/22/1999	V
BD110201	13	4/24/2010	III
BD110201	21	4/29/2010	V
BD110974	3	7/17/2010	Eclipse
BD110974	8	7/24/2010	I
BD110974	9	7/29/2010	II
BD110026	11	7/3/2009	II
BD111065	20	5/31/2002	IV
BD111091	15	8/13/2001	III
BD110450	4	7/20/1999	Eclipse
BM202306	12	11/12/2002	II
BM202263	10	4/25/2002	II
BM202277	16	6/8/2002	III
ER8-2306-0001	14	1/22/1997	III

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HIV-1 RNA

Panel Member	Fiebig Stage	Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 ^{1,2}	Siemens VERSANT® HIV-1 RNA 3.0 Assay (bDNA) ¹
01	Eclipse	Not Detected	Not Detected
02	Eclipse	Not Detected	Not Detected
03	Eclipse	Not Detected	Not Detected
04	Eclipse	Not Detected	Not Detected
05	I	2,718	1228
06	I	289	154
07	I	24,964	13,871
08	I	5,121	2345
09	II	906,509	396,269
10	II	66,454	13,424
11	II	369,347	118,816
12	II	195,079	48,294
13	III	8,427,569	>500,000
14	III	638,261	255,298
15	III	111,168	40,741
16	III	374,308	174,767
17	IV	45,433	10,661
18	IV	2,128,342	>500,000
19	IV	10,000,000	>500,000
20	IV	26,530	7,575
21	V	589,802	370,706
22	V	2,408,243	>500,000
23	V	75,352	9,806
Test Date		09-Sep-14	04-Sep-14
Test Site		RL	RL
Kit Part Code		NA	NA
Kit Lot No.		NA	NA
Kit Exp. Date		NA	NA
Kit Regulatory Status		IVD/CE	IVD/CE

RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

¹Results are reported as copies per mL (c/mL); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

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HIV-1 p24 Antigen and Antigen/Antibody

Panel Member	Fiebig Stage	Perkin Elmer HIV-1 p24 Antigen ELISA ^{1,2}	Abbott ARCHITECT HIV Ag/Ab Combo ^{1,2}	Abbott PRISM HIV Ag/Ab Combo ¹	DiaSorin Murex HIV Ag/Ab Combo ¹
01	Eclipse	0.03	0.08	0.04	0.33
02	Eclipse	0.03	0.13	0.05	0.36
03	Eclipse	0.03	0.13	0.05	0.32
04	Eclipse	0.03	0.09	0.05	0.37
05	I	0.04	0.17	0.08	0.35
06	I	0.03	0.12	0.04	0.33
07	I	0.06	0.62	0.4	0.52
08	I	0.04	0.23	0.1	0.38
09	II	0.75	20.5	10.4	6.5
10	II	1.5	36.3	24.3	10.2
11	II	0.30	8.6	2.9	3.6
12	II	1.6	35.4	17.1	15.3
13	III	2.7	114.9	42.7	16.9
14	III	1.5	25.5	15.7	15.4
15	III	0.56	11.6	5.5	6.7
16	III	3.0	99.8	63.3	13.0
17	IV	0.13	15.2	4.6	12.7
18	IV	2.0	113.3	52.4	17.0
19	IV	3.0	755.4	209.6	15.7
20	IV	0.10	6.3	4.0	8.1
21	V	0.36	42.4	11.3	10.4
22	V	1.4	122.8	49.8	17.9
23	V	0.15	178.4	15.0	14.8
Test Date		15-Sep-14	11-Sep-14	17-Sep-14	10-Sep-14
Test Site		SC	SC	RL	RL
Kit Part Code		NEK 050A/B	2P36	NA	NA
Kit Lot No.		990-13501	40292LI00	NA	NA
Kit Exp. Date		01-Oct-14	09-Feb-15	NA	NA
Kit Regulatory Status		RUO	IVD/CE	IVD/CE	IVD/CE

¹Results are reported as a signal to cut-off value (s/co). Signal to cut-off values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

²Results are reported as the mean result of duplicate testing.

SC = SeraCare; RL = Reference Lab; NA = Not Available; RUO = Research Use Only; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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HIV-1/2 Antibody and Confirmatory

Panel Member	Fiebig Stage	Bio-Rad Genetic Systems™	Fujirebio Innogenetics	OraSure OraQuick®	Bio-Rad Multispot	
		HIV-1/HIV-2 Plus O EIA ^{1,2}	INNO-LIA® HIV I/II Score	ADVANCE Rapid HIV-1/2 Antibody Test ²	HIV-1	HIV-2
01	Eclipse	0.05	NEG	NEG	NEG	NEG
02	Eclipse	0.03	NEG	NEG	NEG	NEG
03	Eclipse	0.04	NEG	NEG	NEG	NEG
04	Eclipse	0.03	NEG	NEG	NEG	NEG
05	I	0.05	NEG	NEG	NEG	NEG
06	I	0.09	NEG	NEG	NEG	NEG
07	I	0.05	NEG	NEG	NEG	NEG
08	I	0.03	NEG	NEG	NEG	NEG
09	II	0.04	NEG	NEG	NEG	NEG
10	II	0.04	NEG	NEG	NEG	NEG
11	II	0.03	NEG	NEG	NEG	NEG
12	II	0.04	NEG	NEG	NEG	NEG
13	III	3.4	NEG	NEG	POS	NEG
14	III	1.8	NEG	NEG	NEG	NEG
15	III	1.2	NEG	NEG	NEG	NEG
16	III	2.0	NEG	NEG	NEG	NEG
17	IV	3.5	IND	WEAK POS	POS	NEG
18	IV	3.6	IND	WEAK POS	POS	NEG
19	IV	3.6	IND	NEG	NEG	NEG
20	IV	3.6	POS	NEG	POS	NEG
21	V	3.6	POS	POS	POS	NEG
22	V	3.7	IND	POS	POS	NEG
23	V	3.7	POS	STRONG POS	POS	NEG
Test Date		08-Sept-14	25-Sep-14	23-Sep-14	12-Sep-14	
Test Site		RL	RL	SC	SC	
Kit Part Code		NA	NA	1001.0079	25228	
Kit Lot No.		NA	NA	6642004	11131158	
Kit Exp. Date		NA	NA	31-Dec-16	05-Jun-14	
Kit Regulatory Status		IVD/CE	CE	IVD	IVD	

¹Results are reported as a signal to cut-off value (s/co). Signal to cut-off values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

²Results are reported as the mean result of duplicate testing.

POS = Positive; IND = Indeterminate; NEG = Negative

SC = SeraCare; RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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HIV-1 Western Blot

Panel Member	Fiebig Stage	HIV-1 Western Blot Interpretation	HIV-1 Western Blot Pattern ³
01	Eclipse	NEG ¹	No Bands
02	Eclipse	NEG ¹	No Bands
03	Eclipse	NEG ¹	No Bands
04	Eclipse	NEG ¹	No Bands
05	I	NEG ¹	No Bands
06	I	NEG ¹	No Bands
07	I	NEG ¹	No Bands
08	I	NEG ¹	No Bands
09	II	NEG ¹	No Bands
10	II	NEG ¹	No Bands
11	II	NEG ¹	No Bands
12	II	NEG ¹	No Bands
13	III	NEG ²	No Bands
14	III	NEG ¹	No Bands
15	III	NEG ²	No Bands
16	III	NEG ¹	No Bands
17	IV	IND ²	<i>p24, p51, p55, gp120, gp160</i>
18	IV	IND ¹	p18, p24, gp160
19	IV	IND ¹	<i>gp41, gp120, gp160</i>
20	IV	IND ¹	<i>gp41, p24</i>
21	V	POS¹	<i>p18, p24, p55, gp160</i>
22	V	POS¹	p18, p24, gp160
23	V	POS¹	<i>p18, p24, gp41, p51, p55, p66, gp120, gp160</i>
Test Date		Various	Various
Test Site		SC	SC
Kit Part Code		NA	NA
Kit Lot No.		NA	NA
Kit Exp. Date		NA	NA
Kit Regulatory Status		IVD	IVD

¹Test performed using the Cambridge Biotech HIV-1 Western Blot Kit.

²Test performed using the Bio-Rad Genetic Systems HIV-1 Western Blot Kit.

³Italicized results demonstrated a (+/-) band intensity.

The Package Insert for this panel in PDF form can be found at www.seracare.com

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