

AccuSet™ HIV-1 Early Infection Performance Panel

0800-0638 / Batch #10798924

OVERVIEW

AccuSet™ HIV-1 Early Infection Performance Panel 0800-0638 / Batch #10798924 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. Each sample represents a single collection event, and in most cases, serial bleeds from the same individual are provided in the panel (see page 2 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. 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.

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

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Fiebig Stage
01	9241475	BD110025	29-Jun-2009	Eclipse
02	10000671	NA	NA	Eclipse
03	BM202159	BD100797	06-Oct-2004	I
04	10418761	BD406214	08-Nov-2018	Eclipse
05	10000670	NA	NA	I
06	9231129	BD106705	09-Apr-2008	I
07	BM216453	BD102986	31-May-2006	I
08	10266923	BD328464	01-Oct-2015	I
09	9241477	BD110025	08-Jul-2009	I or II*
10	9241476	BD110025	06-Jul-2009	I
11	9118514	BD110060	10-Jan-2000	II
12	10000669	NA	NA	II
13	BM202160	BD100797	12-Oct-2004	II
14	BM206239	BD102670	22-May-2006	III
15	10538049	BD459676	03-Jan-2020	IV
16	10266897	BD328454	28-Jul-2016	IV
17	10418763	BD406214	05-Dec-2018	V
18	BM216457	BD102986	14-Jun-2006	IV
19	BM202161	BD100797	21-Oct-2004	V
20	10266924	BD328464	30-Oct-2015	V
21	10418768	BD406218	29-Nov-2018	V
22	10266892	BD328452	18-May-2016	V
23	BM216458	BD102986	21-Jun-2006	V
24	10418767	BD406218	27-Nov-2018	V
25	10266898	BD328454	02-Aug-2016	V

*Member 9 demonstrates low-level reactivity on one of the HIV antigen/antibody combo assays.
NA = Not Available

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HIV RNA and HIV Antigen Assays¹

Panel Member	Roche cobas® 6800/8800 HIV-1 RNA (copies/mL)	Revvity HIV-1 p24 ELISA (S/CO)
01	TND	0.13
02	TND	0.13
03	5.77E+03	0.28
04	TND	0.21
05	9.59E+03	0.40
06	4.60E+03	0.23
07	3.48E+03	0.50
08	2.22E+04	0.51
09	5.58E+04	0.97
10	7.03E+02	0.10
11	7.54E+03	1.73
12	8.76E+05	35.28
13	2.79E+04	4.56
14	8.50E+03	4.49
15	1.94E+03	0.12
16	3.98E+02	0.16
17	7.97E+06, >1.00E+7*	53.42
18	4.83E+05	5.31
19	6.06E+04	6.86
20	4.90E+05	1.41
21	2.05E+03	0.18
22	4.05E+06	28.82
23	1.17E+05	1.49
24	1.37E+03	0.15
25	4.60E+02	0.16
Test Date	17-Jan-2026 20-Jan-2026	19-Jan-2026
Test Site	RL	LGC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-25055
Kit Exp. Date	NA	01-Oct-2026

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

*Interpretation variability. Individual replicates reported.

RL = Reference Lab; LGC = LGC SeraCare; NA = Not Available

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HIV Antigen/Antibody Assays¹

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (S/CO)	Abbott Alinity s HIV Ag/Ab Combo (S/CO)	Abbott Alinity i HIV Combo Next (S/CO)	Roche cobas® Elecsys HIV combi PT (COI)
01	0.17	0.08	0.12	0.29
02	0.16	0.08	0.10	0.27
03	0.26	0.18	0.34	0.31
04	0.22	0.08	0.13	0.30
05	0.50	0.41	0.61	0.36
06	0.22	0.11	0.19	0.33
07	0.21	0.14	0.25	0.27
08	0.32	0.29	0.45	0.36
09	0.73	0.64	1.52	0.61
10	0.26	0.09	0.11	0.26
11	1.17	1.10	2.75	0.94, 1.03*
12	54.95	55.74	97.67	12.67
13	2.84	2.90	6.16	1.85
14	29.05	24.20	22.35	5.24
15	5.39	5.63	17.51	51.59
16	6.39	6.33	6.59	3.70
17	84.78	84.05	134.75	156.35
18	45.35	43.97	41.28	40.22
19	50.50	43.24	31.98	71.24
20	92.10	88.41	45.15	233.10
21	214.32	199.04	128.80	74.47
22	106.75	100.72	134.81	111.75
23	45.12	46.32	24.60	69.51
24	206.27	203.62	136.97	73.29
25	13.58	12.90	12.01	11.55
Test Date	14-Jan-2026	16-Jan-2026	04-Feb-2026	04-Feb-2026 13-Feb-2026
Test Site	LGC	RL	RL	RL
Kit Part Code	2P36	NA	6Q86	NA
Kit Lot No.	78526BE00	80002MM00	81648FZ00	NA
Kit Exp. Date	18-Apr-2026	15-Sep-2026	02-Oct-2026	NA

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AccuSet™ HIV-1 Early Infection Performance Panel

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HIV Antigen/Antibody Rapid Assay¹

Alere Determine™ HIV-1/2 Ag/Ab Combo

Panel Member	HIV Ag	HIV Ab
01	NEG	NEG
02	NEG	NEG
03	NEG	NEG
04	NEG	NEG
05	NEG	NEG
06	NEG	NEG
07	NEG	NEG
08	NEG	NEG
09	NEG	NEG
10	NEG	NEG
11	NEG	NEG
12	POS	NEG
13	NEG	NEG
14	POS	POS
15	NEG	POS
16	NEG	POS
17	NEG	POS
18	NEG	POS
19	POS	POS
20	NEG	POS
21	NEG	POS
22	NEG	POS
23	NEG	POS
24	NEG	POS
25	NEG	POS
Test Date	19-Jan-2026 23-Jan-2026	
Test Site	LGC	
Kit Part Code	7D2648	
Kit Lot No.	0001182809 0001200606	
Kit Exp. Date	20-Aug-2027 17-Oct-2027	

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HIV Antibody Assays¹

Panel Member	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA (S/CO)	Avioq HIV-1 Microelisa (S/CO)
01	0.48	0.20
02	0.35	0.25
03	0.40	0.26
04	0.42	0.22
05	0.57	0.31
06	0.30	0.24
07	0.24	0.24
08	0.30	0.23
09	0.14	0.20
10	0.32	0.21
11	0.97	0.23
12	0.23	0.25
13	0.33	0.22
14	>10.87	1.16
15	10.33	2.71
16	7.41	0.76, 1.19*
17	>10.87	3.23
18	>10.87	3.01
19	>10.87	2.24
20	>10.87	7.09
21	>10.87	4.64
22	>10.87	3.68
23	>10.87	5.19
24	>10.87	5.28
25	9.94	2.59
Test Date	16-Jan-2026	15-Jan-2026
Test Site	LGC	LGC
Kit Part Code	32588	100384
Kit Lot No.	439WBB-05	24107H
Kit Exp. Date	31-Jan-2026	05-Sep-2026

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HIV Confirmatory Assay¹

Bio-Rad HIV-1 Western Blot

Panel Member	HIV-1/2 Antibody Interpretation	Band Results								
		gp120	gp160	p18	p24	p31	gp41	p51	p55	p65
01	NEG	-	-	-	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-	-	-	-
04	NEG	-	-	-	-	-	-	-	-	-
05	NEG	-	-	+/-	-	-	-	-	-	-
06	NEG	-	-	-	-	-	-	-	-	-
07	NEG	-	-	-	-	-	-	-	-	-
08	NEG	-	-	-	-	-	-	-	-	-
09	NEG	-	-	-	-	-	-	-	-	-
10	NEG	-	-	-	-	-	-	-	-	-
11	NEG	-	-	-	-	-	-	-	-	-
12	NEG	-	-	-	-	-	-	-	-	-
13	NEG	-	-	-	-	-	-	-	-	-
14	NEG	-	-	-	-	-	-	-	-	-
15	IND	-	+/-	+	++	+/-	+/-	-	++	-
16	IND	-	+/-	+/-	++	-	-	-	+	-
17	POS	-	+	+	++	-	+/-	-	+	-
18	IND	+/-	+	+/-	+/-	-	-	-	-	-
19	POS	+/-	+	+/-	+	-	-	-	+/-	-
20	POS	+/-	+	+/-	++	+/-	-	-	+	-
21	POS	+/-	+	+/-	++	+/-	+/-	-	++	-
22	POS	-	+	-	+	-	-	-	+/-	-
23	POS	-	+	+/-	++	-	-	-	+	-
24	POS	-	+	+/-	++	+/-	+/-	-	++	-
25	POS	-	+	+	++	-	+/-	-	+	-
Test Date					04-Mar-2026					
					06-Mar-2026					
Test Site					LGC					
Kit Part Code					32508					
Kit Lot No.					64691715					
Kit Exp. Date					17-Sep-2026					

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LGC = LGC SeraCare; POS = Positive; NEG = Negative; IND = Indeterminate

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HIV Confirmatory Assay¹

INNOGENETICS® INNO-LIA™ HIV I/II Score

Band Results

Panel Member	HIV-1/2 Antibody	sgp120	gp41	p31	p24	p17	sgp105	gp36
	Interpretation							
01	NEG	-	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-	-
04	NEG	-	-	-	-	-	-	-
05	NEG	-	-	-	-	-	-	-
06	NEG	-	-	-	-	-	-	-
07	NEG	-	-	-	-	-	-	-
08	NEG	-	-	-	-	-	-	-
09	NEG	-	-	-	-	-	-	-
10	NEG	-	-	-	-	-	-	-
11	NEG	-	-	-	-	-	-	-
12	NEG	-	-	-	-	-	-	-
13	NEG	-	-	-	-	-	-	-
14	IND	-	2+	-	-	-	-	-
15	POS	1+	2+	-	3+	2+	-	-
16	POS	1+	2+	-	2+	-	-	-
17	POS	-	2+	-	2+	1+	-	-
18	IND	-	2+	-	-	-	-	-
19	POS	2+	2+	-	1+	-	-	-
20	POS	2+	3+	-	2+	2+	-	-
21	POS	-	2+	-	2+	2+	-	-
22	POS	2+	2+	-	1+	-	-	-
23	POS	-	2+	-	2+	1+	-	-
24	POS	-	2+	-	3+	2+	-	-
25	POS	1+	2+	-	2+	1+	-	-
Test Date	30-Jan-2026							
Test Site	RL							
Kit Part Code	NA							
Kit Lot No.	297209							
Kit Exp. Date	31-Dec-2026							

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red.

RL = Reference Lab; NA = Not Available; POS = Positive;

NEG = Negative; IND = Indeterminate

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.