

AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0596 / Batch # 10742367

OVERVIEW

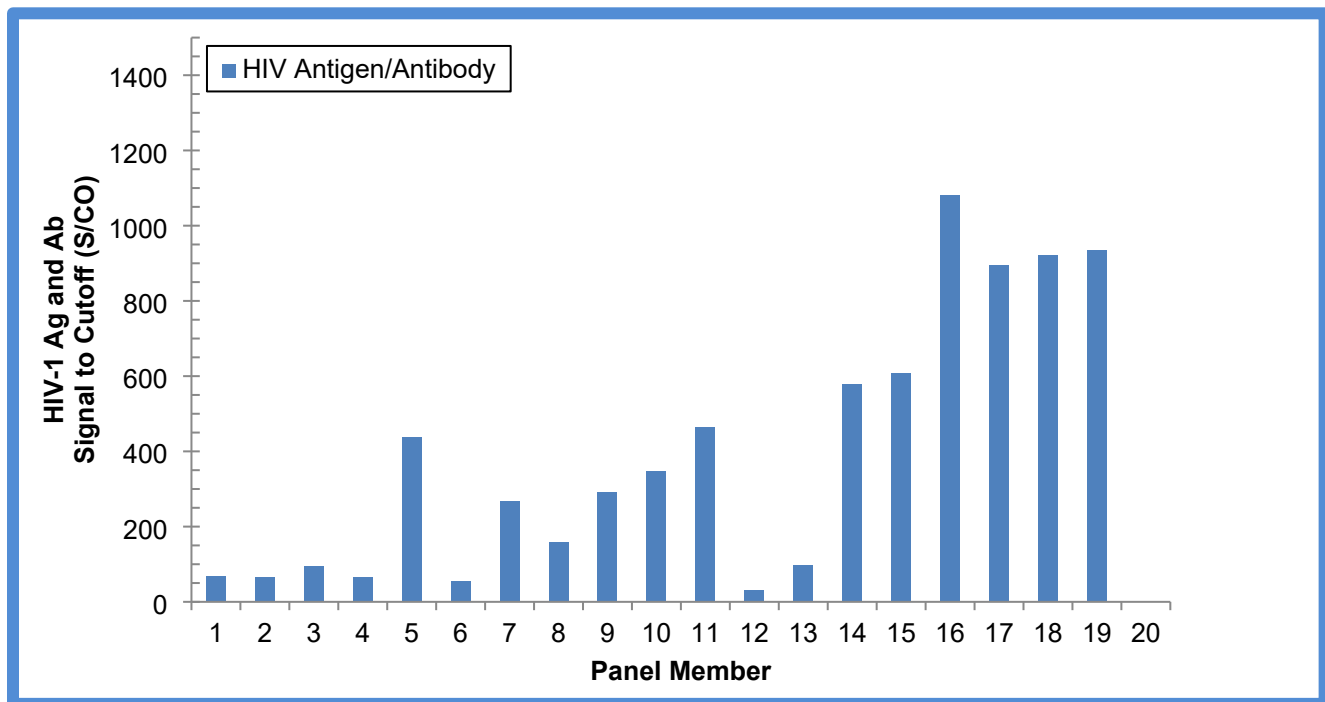
AccuSet™ HIV-1 Mixed Titer Performance Panel 0800-0596 / Batch #10742367 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HIV-1. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV-1 assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity for HIV-1. 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 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 Mixed Titer Performance Panel



This graph demonstrates the relative titer amongst panel members with the Abbott Alinity s HIV Antigen/Antibody Combo test method.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9253902	BD111102	04-Jul-2000
02	10418766	BD406217	27-Sep-2018
03	10430531	BD407035	22-Mar-2019
04	10430534	BD407035	24-Mar-2019
05	10481640	BD428650	26-Aug-2019
06	10266924	BD328464	30-Oct-2015
07	10662631	BD519638	11-Oct-2018
08	10418768	BD406218	29-Nov-2018
09	10662636	BD519643	15-Sep-2021
10	10653011	BD512778	10-Mar-2020
11	10653014	BD512781	24-Sep-2022
12	9251513	BD111003	05-Jul-2000
13	10266902	BD328456	29-Oct-2015
14	10662635	BD519642	14-Aug-2021
15	10662634	BD519641	22-Jun-2021
16	9253709	BD111011	07-Sep-2000
17	10653012	BD512779	24-Jul-2021
18	10653017	BD512784	09-Mar-2018
19	10653018	BD512785	08-Jan-2018
20	9192330	NA	NA

NA = Not Available

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HIV RNA and HIV Antigen Assays

Panel Member	Roche cobas® 6800/8800 HIV-1 RNA (copies/mL) ¹	Revvity HIV-1 p24 ELISA (S/CO) ¹
01	1.88E+04	1.26
02	1.50E+04	0.18
03	2.07E+05	1.34
04	9.47E+04	0.92
05	7.75E+03	0.08
06	3.98E+05	1.01
07	TND	0.10
08	2.52E+03	0.06
09	1.38E+05	0.14
10	3.74E+04	0.14
11	1.27E+04	0.09
12	TND	0.06
13	1.70E+04	0.10
14	1.44E+03	0.05
15	4.12E+04	0.05
16	6.08E+02	0.13
17	1.51E+04	1.37
18	5.18E+04	3.80
19	9.22E+02	0.03
20	TND	0.08
Test Date	20-Mar-2025	19-Mar-2025
Test Site	RL	LGC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-25051
Kit Exp. Date	NA	01-Jan-2026

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.
RL = Reference Lab; LGC = LGC SeraCare; NA = Not Available

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HIV Antigen/Antibody Assays

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (S/CO) ¹	Abbott Alinity s HIV Ag/Ab Combo (S/CO) ¹	Abbott Alinity i HIV Combo Next (S/CO) ¹	Roche cobas® Elecsys HIV combi PT (COI) ¹
01	85.94	66.91	16.67	82.47
02	81.93	66.33	195.56	6.53
03	142.78	95.08	46.59	21.05
04	87.21	65.96	29.16	24.60
05	428.79	437.39	186.65	1176.00
06	69.51	55.43	42.41	211.05
07	282.95	268.45	117.62	2495.00
08	195.74	158.48	133.92	72.31
09	323.11	291.16	113.65	414.30
10	347.85	347.32	146.95	825.95
11	407.06	465.14	177.32	1559.00
12	34.97	31.65	23.36	155.65
13	110.34	96.32	54.59	207.35
14	579.16	578.80	241.67	533.70
15	633.37	607.20	270.42	578.85
16	1013.87	1081.45	482.65	487.10
17	894.51	894.00	384.54	1989.50
18	930.28	921.33	408.11	1709.50
19	984.58	934.39	438.88	990.95
20	0.37	0.31	0.26	0.31
Test Date	19-Mar-2025	20-Mar-2025	02-Dec-2025	02-Apr-2025
Test Site	LGC	RL	RL	RL
Kit Part Code	2P36	NA	6Q86	NA
Kit Lot No.	71282BE00	68244BE00	81648FZ00	NA
Kit Exp. Date	24-Aug-2025	09-Sep-25	02-Oct-2026	NA

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AccuSet™ HIV-1 Mixed Titer Performance Panel

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HIV Antigen/Antibody Assays

Panel Member	Siemens Advia Centaur® HIV Ag/Ab Combo	Avioq HIV-1 Microelisa	Alere Determine™ HIV-1/2 Ag/Ab Combo ²	
	(Index) ¹	(S/CO) ¹	HIV Ag	HIV Ab
01	4.75	6.16	NEG	POS
02	10.14	4.55	NEG	POS
03	3.74	4.19	NEG	POS
04	3.62	4.05	NEG	POS
05	>12.00	7.57	NEG	POS
06	5.83	6.27	NEG	POS
07	>12.00	7.47	NEG	POS
08	8.79	5.15	NEG	POS
09	>12.00	7.63	NEG	POS
10	>12.00	7.58	NEG	POS
11	>12.00	7.88	NEG	POS
12	11.22	6.28	NEG	POS
13	8.56	7.00	NEG	POS
14	>12.00	7.74	NEG	POS
15	>12.00	8.21	NEG	POS
16	>12.00	7.93	NEG	POS
17	>12.00	8.21	NEG	POS
18	>12.00	7.96	NEG	POS
19	>12.00	8.05	NEG	POS
20	0.06	0.30	NEG	NEG
Test Date	27-Mar-2025	20-Mar-2025	21-Apr-2025	
Test Site	RL	LGC	LGC	
Kit Part Code	NA	100384	7D2648	
Kit Lot No.	58444365	24102H	845391	
Kit Exp. Date	03-Aug-2025	25-Apr-2026	28-Jul-2025	

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

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AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0596 / Batch # 10742367

HIV Confirmatory Assay

INNOGENETICS® INNO-LIA™ HIV I/II Score¹

Band Results

Panel Member	HIV-1/2 Antibody	sgp120	gp41	p31	p24	p17	sgp105	gp36
	Interpretation							
01	POS	2+	2+	1+	2+	2+	-	-
02	POS	2+	3+	-	2+	1+	-	-
03	POS	-	3+	-	2+	+/-	-	-
04	POS	-	3+	-	3+	1+	-	-
05	POS	2+	3+	2+	3+	2+	-	-
06	POS	2+	3+	-	2+	2+	-	-
07	POS	2+	2+	2+	2+	1+	-	-
08	POS	-	2+	-	3+	2+	-	-
09	POS	2+	3+	2+	3+	2+	-	-
10	POS	2+	3+	2+	2+	2+	-	-
11	POS	2+	3+	2+	3+	3+	-	-
12	POS	2+	2+	-	3+	2+	-	-
13	POS	2+	3+	2+	2+	2+	-	-
14	POS	3+	3+	2+	3+	3+	-	-
15	POS	2+	3+	2+	3+	3+	-	-
16	POS	3+	3+	-	2+	2+	-	1+
17	POS	3+	3+	2+	2+	-	-	-
18	POS	2+	3+	2+	2+	1+	-	-
19	POS	3+	3+	2+	3+	3+	-	-
20	NEG	-	-	-	-	-	-	-

Test Date 28-Mar-2025

Test Site RL

Kit Part Code NA

Kit Lot No. 291239

Kit Exp. Date 31-Aug-2025

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

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HIV Confirmatory Assay

Bio-Rad HIV-1 Western Blot¹

Panel Member	HIV-1/2 Antibody Interpretation	Band Results								
		gp120	gp160	p18	p24	p31	gp41	p51	p55	p65
01	POS	+/-	+	-	++	+/-	-	-	++	-
02	IND	-	+/-	-	++	-	-	-	+	-
03	POS	-	+	+/-	++	-	-	-	++	-
04	POS	-	+	+/-	++	-	-	-	++	-
05	POS	+	++	+	++	+	++	-	++	++
06	POS	+/-	++	+/-	++	-	-	-	++	-
07	POS	+	++	-	++	+	+/-	-	++	++
08	POS	+/-	+	+/-	++	+/-	+/-	-	++	-
09	POS	+	++	+	++	++	+	-	++	++
10	POS	+	++	-	++	+	+	-	+	+
11	POS	+	++	++	++	++	++	-	++	++
12	POS	-	+	+/-	++	+/-	+/-	-	++	-
13	POS	+/-	++	+/-	++	++	-	-	+	+
14	POS	+	++	+	++	++	++	-	++	++
15	POS	+	++	++	++	++	++	-	++	++
16	POS	+	++	-	+	-	++	-	+/-	+/-
17	POS	++	++	+/-	+	++	++	-	++	++
18	POS	++	++	+/-	+/-	++	++	-	++	++
19	POS	++	++	++	++	++	++	-	++	++
20	NEG	-	-	+/-	-	-	-	-	-	-
Test Date	24-Mar-2025									
Test Site	LGC									
Kit Part Code	32508									
Kit Lot No.	64613206									
Kit Exp. Date	30-Jun-2025									

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LGC = LGC SeraCare; 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.