

AccuSet[™] HIV-1 Low Titer Performance Panel

0800-0617 / Batch #10754862

OVERVIEW

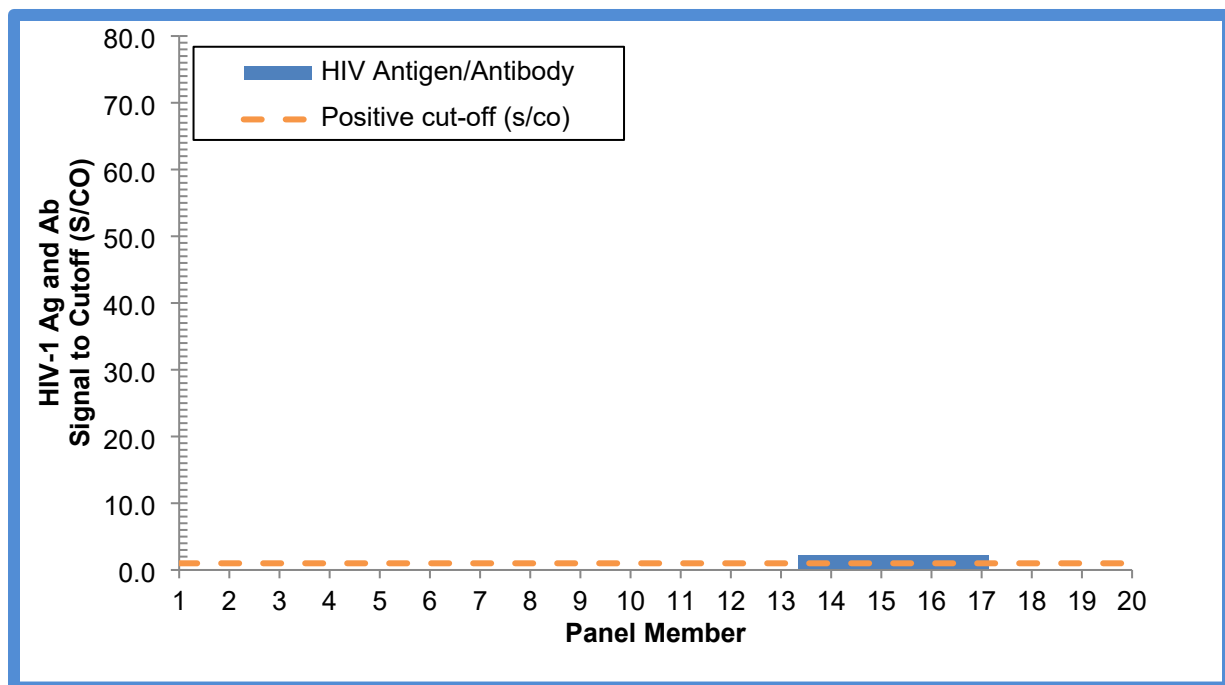
AccuSet[™] HIV-1 Low Titer Performance Panel 0800-0617 / Batch #10754862 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HIV-1. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity which approach the sensitivity limits for several anti-HIV-1 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 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 Low Titer Performance Panel



This graph demonstrates panel member reactivity to the Abbott ARCHITECT HIV Ag/Ab test method.

AccuSet™ HIV-1 Low Titer
Performance Panel
0800-0617 / Batch #10754862

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	BM204548	BD101687	09-Dec-2005
02	BM202160	BD100797	12-Oct-2004
03	10481821	BD428658	21-Oct-2019
04	10266896	BD328454	26-Jul-2016
05	10401945	BD398598	12-Sep-2018
06	10418765	BD406216	07-Dec-2018
07	10418769	BD406219	09-Nov-2018
08	10418770	BD406220	02-Nov-2018
09	10418771	BD406220	31-Oct-2018
10	10430525	BD407032	21-Mar-2019
11	10430527	BD407034	25-Oct-2018
12	10430530	BD407033	14-Feb-2019
13	10497506	BD436958	23-Dec-2019
14	9230846	BD106689	29-Apr-2008
15	10481825	BD428658	24-Oct-2019
16	10496666	BD436229	09-Aug-2019
17	10481826	BD428660	01-Jan-2020
18	10440665	BD411043	31-May-2019
19	10538050	BD459677	27-Feb-2020
20	10325465	BD357889	08-Feb-2014

AccuSet™ HIV-1 Low Titer Performance Panel

0800-0617 / Batch #10754862

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	1.85E+05	3.66
02	2.61E+04	3.55
03	7.05E+03	0.12
04	5.09E+02	0.08
05	1.51E+04	0.18
06	5.46E+03	0.09
07	1.19E+05	0.36
08	1.29E+04	0.13
09	1.22E+04	0.17
10	1.44E+05	1.40
11	3.27E+04	0.15
12	1.44E+04	0.40
13	1.44E+04	0.29
14	2.17E+04	0.14
15	6.94E+03	0.11
16	1.31E+05	1.45
17	1.34E+06	16.10
18	2.27E+06	5.43
19	3.43E+05	0.94, 1.00*
20	TND	0.11
Test Date	14-May-2025	13-May-2025
Test Site	RL	LGC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-25111
Kit Exp. Date	NA	01-Dec-2025

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 Clinical Diagnostics; NA = Not Available

AccuSet™ HIV-1 Low Titer Performance Panel

0800-0617 / Batch #10754862

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	2.22	2.24	6.00	1.45
02	2.67	2.80	5.78	1.43
03	15.16	11.65	29.56	116.85
04	5.57	4.26	5.28	3.08
05	56.94	42.11	44.10	133.95
06	34.79	26.47	43.17	133.80
07	9.95	8.08	5.53	25.83
08	54.63	42.47	40.17	86.58
09	43.38	32.78	32.89	77.99
10	33.17	26.11	31.45	30.97
11	77.81	42.91	35.65	170.85
12	12.75	8.99	7.13	20.30
13	16.69	13.33	30.26	138.05
14	25.68	22.04	27.16	117.95
15	27.00	20.28	36.60	150.85
16	24.05	18.55	28.60	234.40
17	30.68	26.23	38.72	47.50
18	9.14	7.94	18.93	34.24
19	13.53	10.84	34.33	74.04
20	0.18	0.08	0.09	0.17
Test Date	12-May-2025	08-May-2025	02-Dec-2025	04-Jun-2025
Test Site	LGC	RL	RL	RL
Kit Part Code	2P36	NA	6Q86	NA
Kit Lot No.	74195BE00	68244BE00	81648FZ00	NA
Kit Exp. Date	14-Nov-2025	09-Sep-2025	02-Oct-2026	NA

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

AccuSet™ HIV-1 Low Titer Performance Panel

0800-0617 / Batch #10754862

HIV Antigen/Antibody Assays

Panel Member	Bio-Rad GS HIV-1/HIV-2 Plus O EIA (S/CO) ¹	Avioq HIV-1 Microelisa (S/CO) ¹	OraSure OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test ²
01	0.12	0.27	NEG
02	0.28	0.25	NEG
03	13.95, >14.18*	4.07	POS
04	13.64	1.38	POS
05	>14.18	4.77	POS
06	>14.18	5.59	POS
07	>14.18	4.50	POS
08	>14.18	3.57	POS
09	>14.18	2.89	POS
10	>14.18	2.79	POS
11	>14.18	7.24	POS
12	>14.18	3.57	POS
13	>14.18	4.22	POS
14	>14.18	4.10	POS
15	>14.18	4.52	POS
16	>14.18	6.98	POS
17	13.13, >14.18*	2.98	POS
18	>14.18	2.81	POS
19	13.73	6.39	POS
20	0.16	0.30	NEG
Test Date	08-May-2025	09-May-2025	12-May-2025
Test Site	LGC	LGC	LGC
Kit Part Code	32588	100384	1001.0079
Kit Lot No.	434WBB-05	24102H	0006722227
Kit Exp. Date	30-Nov-2025	25-Apr-2026	31-Jul-2025

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

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

*Interpretation variability; individual replicates reported.

LGC = LGC Clinical Diagnostics

AccuSet™ HIV-1 Low Titer Performance Panel

0800-0617 / Batch #10754862

HIV Confirmatory Assay

INNOGENETICS® INNO-LIA™ HIV I/II Score¹

Band Results

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

Test Date 30-May-2025

Test Site RL

Kit Part Code NA

Kit Lot No. 292584

Kit Exp. Date 31-Jan-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

AccuSet™ HIV-1 Low Titer Performance Panel

0800-0617 / Batch #10754862

HIV Confirmatory Assay

Bio-Rad HIV-1 Western Blot¹

Panel Member	HIV-1/2 Antibody Interpretatio	Band Results								
		gp120	gp160	p18	p24	p31	gp41	p51	p55	p65
01	IND	-	-	+/-	-	-	-	-	-	-
02	IND	-	-	+/-	-	-	-	-	-	-
03	POS	-	+	+/-	++	-	-	-	+	-
04	IND	-	+/-	+/-	++	-	-	-	+	-
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	IND	-	+/-	+/-	++	-	+/-	-	++	-
19	IND	-	+/-	-	++	-	-	-	+/-	-
20	NEG	-	-	-	-	-	-	-	-	-
Test Date	08-May-2025									
Test Site	LGC									
Kit Part Code	32508									
Kit Lot No.	64613206									
Kit Exp. Date	30-Jun-2025									

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