

AccuSet™ HIV-1/2 Performance Panel

0800-0508 / Batch 10576810

OVERVIEW

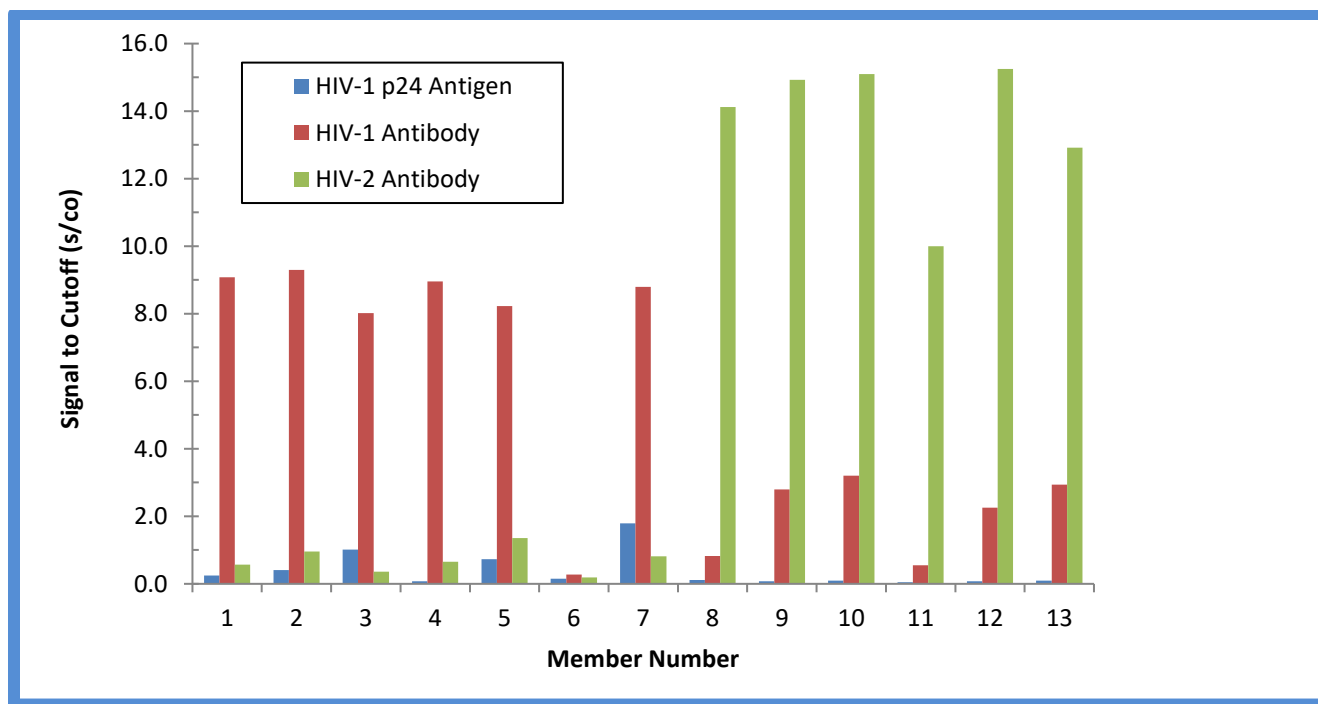
AccuSet™ HIV-1/2 Performance Panel (0800-0508) Batch 10576810 is a 13-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HIV. Each sample represents a single collection 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. 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-1/2 Performance Panel - Batch 10576810



This graph demonstrates panel member reactivity to the Perkin Elmer HIV-1 p24 Antigen EIA (HIV-1 p24 Antigen), Avioq HIV-1 microelisa (HIV-1 Antibody), and the Bio-Rad GS HIV-2 EIA (HIV-2 Antibody) test methods.

AccuSet™ HIV-1/2 Performance Panel

0800-0508 / Batch 10576810

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	BM206260	BD102725	19-Jun-2006
02	10000723	BD217616	09-Nov-1998
03	10000751	BD217613	07-Nov-1997
04	10112113	BD240183	15-Dec-2014
05	10000787	NA	NA
06	10310079	BD349121	05-Jun-2017
07	9117875	BD110619	NA
08	10420832	BD406473	13-Jan-2013
09	10431584	BD409489	30-Jan-2019
10	10431587	BD409489	02-Apr-2019
11	10511894	BD110417	30-Sep-2019
12	10537563	NA	NA
13	10566397	BD328433	30-May-2014

NA = Not Available

HIV-1 RNA, HIV Antigen, and HIV Antigen/Antibody assays

Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v 2.0 (copies/mL) ¹	PerkinElmer HIV-1 p24 core Antigen ELISA (S/CO) ¹	Abbott Architect HIV Ag/Ab Combo (S/CO) ¹	Roche cobas® Eleclys HIV combi PT (COI) ¹
01	539	0.25	1,313.69	542.50
02	282	0.41	1,308.06	1,892.50
03	4,336	0.95, 1.09 *	782.72	1,006.50
04	2,845	0.08	1,343.25	1,402.50
05	87 , TND *	0.73	229.02	2,925.50
06	TND	0.15	0.12	0.22
07	4,528	1.79	1,030.89	22.40
08	TND	0.12	192.75	553.50
09	TND	0.08	157.75	255.00
10	TND	0.10	154.91	253.50
11	TND	0.05	92.77	5,477.00
12	TND	0.07	147.74	174.00
13	TND	0.10	154.43	1,997.50
Test Date	08-Nov-2021	21-Oct-2021	20-Oct-2021	08-Nov-2021
Test Site	RL	SC	SC	RL
Kit Part Code	NA	NEK050B	2P36	NA
Kit Lot No.	G33450	990-21091	29307BE00	NA
Kit Exp. Date	31-Aug-2022	01-Mar-2022	01-Mar-2022	NA

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

*Interpretation variability based on duplicate testing, individual replicates reported.

TND = Target Not Detected; SC = SeraCare; RL = Reference Lab; NA = Not Available

AccuSet™ HIV-1/2 Performance Panel

0800-0508 / Batch 10576810

HIV Antigen/Antibody assays (continued)

Panel Member	Abbott Alinity i HIV Ag/Ab Combo	Ortho VITROS HIV Combo	Siemens Advia Centaur® HIV Ag/Ab Combo	Alere Determine™ HIV-1/2 Ag/Ab Combo ²	
	(S/CO) ¹	(S/CO) ¹	(Index) ¹	HIV Ag	HIV Ab
01	1,135.32	100.00	> 12.00	NEG	POS
02	1,162.54	368.50	> 12.00	NEG	POS
03	710.17	99.70	> 12.00	NEG	POS
04	1,201.63	138.00	> 12.00	NEG	POS
05	200.15	118.00	> 12.00	NEG	POS
06	0.08	0.09	< 0.05	NEG	NEG
07	909.97	205.00	> 12.00	NEG	POS
08	178.81	49.45	> 12.00	NEG	POS
09	139.43	44.75	> 12.00	NEG	POS
10	140.62	46.30	> 12.00	NEG	POS
11	84.91	49.70	> 12.00	NEG	POS
12	135.49	44.25	> 12.00	NEG	POS
13	136.15	48.50	8.56	NEG	POS
Test Date	05-Nov-2021	23-Nov-2021	05-Nov-2021	22-Oct-2021	
Test Site	RL	RL	RL	SC	
Kit Part Code	NA	NA	NA	7D2648	
Kit Lot No.	29335BE00	0320	304	161743	
Kit Exp. Date	01-Mar-2022	04-Aug-2022	16-Apr-2022	02-Dec-2022	

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

²Results are reported as singlicate testing.

SC = SeraCare; RL = Reference Lab; NA = Not Available; POS = Positive; NEG = Negative

AccuSet™ HIV-1/2
Performance Panel
0800-0508 / Batch 10576810

HIV-1 Antibody, HIV-2 Antibody assays

Panel Member	Avioq HIV-1 Microelisa (S/CO) ¹	Bio-Rad GS HIV-2 EIA (S/CO) ¹
01	9.08	0.56
02	9.30	0.85, 1.07 *
03	8.02	0.36
04	8.95	0.66
05	8.22	1.36
06	0.27	0.19
07	8.79	0.81
08	0.82	14.12
09	2.80	14.93
10	3.20	15.09
11	0.55	9.99
12	2.26	15.25
13	2.93	12.92
Test Date	20-Oct-2021	22-Oct-2021
Test Site	SC	SC
Kit Part Code	100384	32536
Kit Lot No.	20103H	124RY1-05
Kit Exp. Date	17-Nov-2021	07-Jan-2022

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

*Interpretation variability based on duplicate testing, individual replicates reported.

SC = SeraCare

AccuSet™ HIV-1/2
Performance Panel
0800-0508 / Batch 10576810

HIV-1/2 Supplemental Assay

Bio-Rad Geenius™ HIV 1/2 Supplemental Assay ¹			
Panel Member	HIV-1 Result	HIV-2 Result	Positive Bands
01	POS	NEG	p31, gp160, p24, gp41
02	POS	NEG	p31, gp160, gp41
03	POS	NEG	p31, gp160, gp41
04	POS	NEG	p31, gp160, gp41
05	POS	NEG	p31, gp160, gp41
06	NEG	NEG	no bands
07	POS	NEG	p31, gp160, gp41
08	IND	POS	gp36, gp140, p31
09	POS *	POS	gp36, gp140, p31, gp41
10	POS *	POS	gp36, gp140, p31, gp41
11	IND	POS	gp36, gp140, p31
12	POS *	POS	gp36, gp140, p31, gp41
13	POS *	POS	gp36, gp140, gp160, p24, gp41
Test Date		22-Oct-2021	
Test Site		RL	
Kit Part Code		NA	
Kit Lot No.		1E0056	
Kit Exp. Date		28-Apr-2023	

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

*HIV-2 Positive with HIV-1 cross-reactivity.

RL = Reference Lab; NA = Not Available; POS = Positive; NEG = Negative; IND = Indeterminate

AccuSet™ HIV-1/2
Performance Panel
0800-0508 / Batch 10576810

HIV-1/2 Confirmatory Assay

INNOGENETICS® INNO-LIA™ HIV I/II Score¹

Panel Member	HIV-1/2 Antibody Interpretation	Band Results						
		sgp120	gp41	p31	p24	p17	sgp105	gp36
01	HIV-1 POS	3+	4+	2+	2+	3+	-	-
02	HIV-1 POS	3+	4+	3+	1+	1+	-	-
03	HIV-1 POS	2+	3+	2+	1+	-	-	-
04	HIV-1 POS	3+	4+	3+	2+	3+	-	-
05	HIV-1 POS	2+	3+	2+	3+	3+	-	-
06	NEG	-	-	-	-	-	-	-
07	HIV-1 POS	2+	4+	2+	2+	2+	-	-
08	HIV-2 POS	-	-	2+	1+	-	3+	3+
09	HIV-2 POS	-	-	2+	2+	2+	3+	3+
10	HIV-2 POS	-	-	2+	2+	1+	3+	3+
11	HIV-2 POS	-	-	2+	±	-	1+	2+
12	HIV-2 POS	-	-	2+	2+	1+	3+	3+
13	HIV-2 POS	-	-	2+	2+	1+	3+	3+
Test Date	23-Nov-2021							
Test Site	RL							
Kit Part Code	NA							
Kit Lot No.	408491							
Kit Exp. Date	31-May-2022							

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red.
RL = Reference Lab; NA = Not Available; POS = Positive; NEG = Negative

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.