

AccuSet™ HCV Verification Panel 1

0810-0325 / Batch #10670480

OVERVIEW

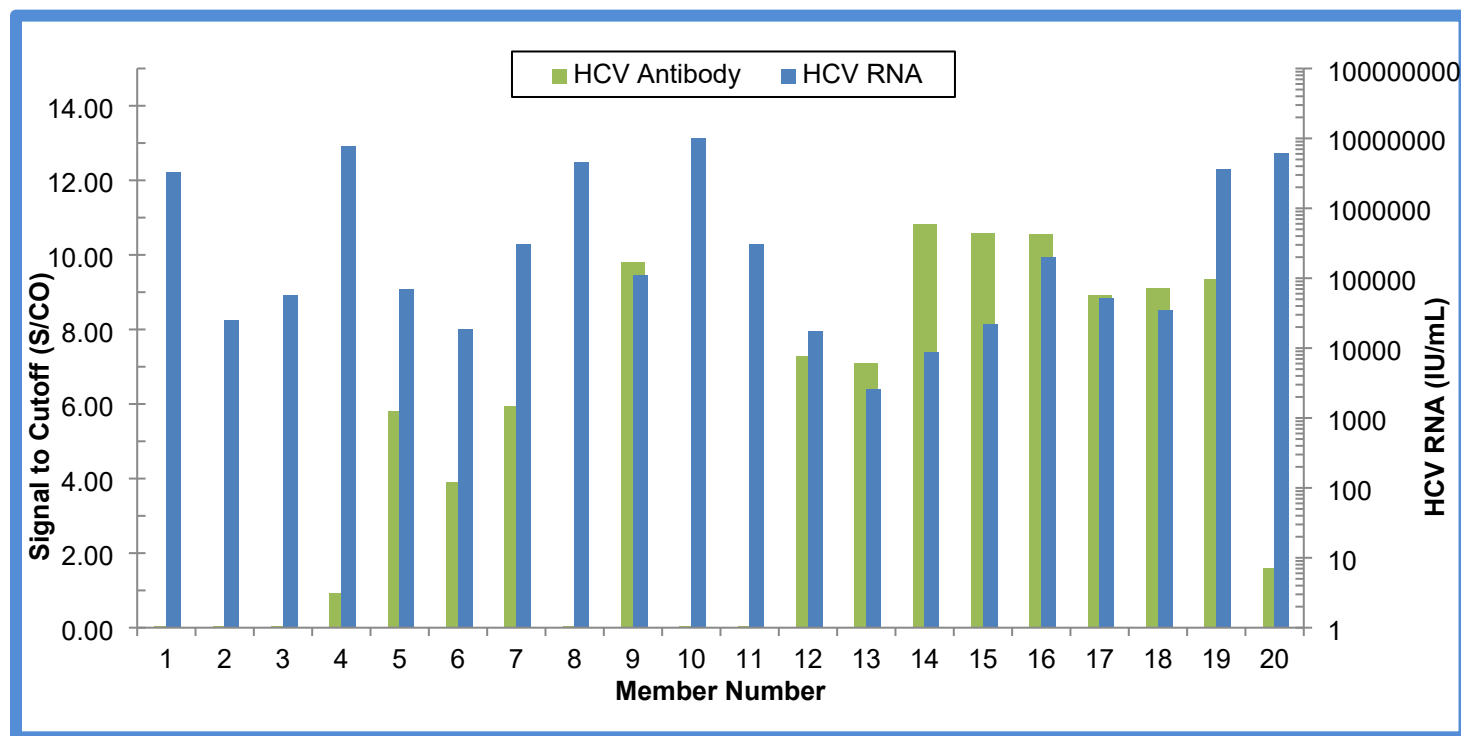
AccuSet™ HCV Verification Panel 1, 0810-0325 / Batch #10670480, is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL per vial). Panel members represent bleeds from multiple individuals positive for HCV. Each sample represents a single collection event. No preservatives were added.

Test results from commercially available HCV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of HCV RNA and anti-HCV reactivity.

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 HCV; all were found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates reactivity amongst panel members from the Roche cobas® (HCV RNA) and Abbott Alinity s (Anti-HCV) test methods.

AccuSet™ HCV
Verification Panel 1
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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9232114	NA	13-Jun-2008
02	9232130	NA	21-Jul-2008
03	9242374	0451067043	21-Jul-2009
04	9106297	LU007348	29-Jan-2000
05	10456790	19500611255	04-Jul-2019
06	10456791	19500609884	02-Jul-2019
07	10456792	14902042021	30-Jul-2019
08	10329400	01206024564	04-Dec-2017
09	9148706	27046427	24-Jan-2003
10	10354471	14401702618	05-Apr-2018
11	9216276	0090822700	30-Jun-2007
12	10395933	62709629791	04-Dec-2018
13	10395934	62709953903	06-Dec-2018
14	9154306	NA	NA
15	9154307	NA	NA
16	9230521	0608A063	NA
17	10430536	21100117840	01-Nov-2018
18	10430538	21100110550	28-Oct-2018
19	10440668	18900800018	16-Apr-2019
20	9106298	LU007365	01-Feb-2000

NA = Not Available

AccuSet™ HCV

Verification Panel 1

0810-0325 / Batch #10670480

HCV RNA¹

Panel Member	Roche cobas® 6800/8800 HCV RNA (IU/mL)	Abbott Alinity m HCV RNA (IU/mL)
01	3.28E+06	3.19E+06
02	2.52E+04	3.08E+04
03	5.72E+04	7.59E+04
04	7.68E+06	6.70E+06
05	6.93E+04	8.27E+04
06	1.85E+04	2.09E+04
07	3.09E+05	3.50E+05
08	4.63E+06	4.65E+06
09	1.10E+05	1.03E+05
10	1.01E+07	9.83E+06
11	3.11E+05	2.99E+05
12	1.77E+04	2.07E+04
13	2.59E+03	2.40E+03
14	8.77E+03	9.06E+03
15	2.20E+04	2.41E+04
16	2.01E+05	1.71E+05
17	5.13E+04	4.66E+04
18	3.47E+04	3.21E+04
19	3.63E+06	3.43E+06
20	6.05E+06	7.46E+06
Test Date	07-Jul-2023	10-Jul-2023
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	NA	385356
Kit Exp. Date	NA	10-Feb-2025

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

RL = Reference Lab; NA = Not Available

AccuSet™ HCV

Verification Panel 1

0810-0325 / Batch #10670480

HCV Antibody and HCV Antigen¹

Panel Member	Abbott ARCHITECT Anti-HCV (S/CO)	Abbott Alinity s Anti-HCV (S/CO)	Abbott Alinity s Anti-HCV II (S/CO)	Abbott Alinity i Anti-HCV Next (S/CO)	Roche cobas® Elecsys Anti-HCV II (COI)	Abbott ARCHITECT HCV Ag (fmol/L)
01	0.07	0.03	0.10	0.10	0.06	1.03E+04
02	0.09	0.04	0.08	0.05	0.07	2.81E+03
03	0.05	0.03	0.05	0.01	0.06	5.20E+02
04	2.55	0.85, 1.00*	1.05	1.77	1.32	1.30E+04
05	7.57	5.80	43.72	61.60	184.15	1.07E+02
06	4.85	3.90	41.45	58.67	138.20	3.65E+01
07	8.44	5.93	28.34	53.77	126.80	5.86E+02
08	0.07	0.04	0.10	0.09	0.08	4.36E+03
09	15.17	9.80	39.95	56.58	21.06	1.20E+03
10	0.09	0.05	0.10	0.07	0.07	>2.00E+04
11	0.06	0.03	0.05	0.02	0.08	1.09E+03
12	10.09	7.29	33.05	55.18	152.55	1.69E+01
13	9.55	7.10	35.22	58.21	147.85	1.18E+00
14	16.33	10.82	40.20	43.36	19.62	1.86E+03
15	16.19	10.57	36.96	43.37	21.26	8.06E+02
16	14.02	10.55	53.84	59.92	87.51	1.06E+03
17	13.39	8.92	23.30	42.26	32.56	3.08E+01
18	13.42	9.10	18.48	37.13	19.66	4.54E+01
19	11.32	9.36	29.17	36.42	121.50	3.30E+03
20	3.28	1.59	9.01	17.71	34.34	1.09E+04
Test Date	05-Jul-2023	07-Jul-2023	18-Oct-2024	02-May-2025	01-Aug-2023	19-Jul-2023
Test Site	LGC	RL	RL	RL	RL	RL
Kit Part Code	1L79	NA	NA	NA	NA	NA
Kit Lot No.	47588BE00	50274BE00	62454BE00	69065BE00	NA	51301LP76
Kit Exp. Date	15-Nov-2023	09-Feb-2024	28-Apr-2025	17-Sep-2025	NA	02-Mar-2024

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™ HCV

Verification Panel 1

0810-0325 / Batch #10670480

HCV Confirmatory Assay

INNOGENETICS® INNO-LIA™ HCV Score¹

Band Results

Panel Member	HCV Antibody Interpretation	C1	C2	E2	NS3	NS4	NS5
01	NEG	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-
04	POS	1+	±	-	-	-	-
05	POS	-	-	-	2+	2+	-
06	POS	-	-	-	2+	2+	-
07	IND	-	-	-	2+	-	-
08	NEG	-	-	-	-	-	-
09	POS	2+	2+	1+	4+	4+	4+
10	NEG	-	-	-	-	-	-
11	NEG	-	-	-	-	-	-
12	POS	1+	-	-	2+	-	-
13	POS	±	-	-	2+	-	-
14	POS	4+	2+	-	4+	4+	4+
15	POS	4+	2+	-	4+	4+	4+
16	POS	3+	1+	-	4+	-	2+
17	POS	-	1+	1+	4+	4+	2+
18	POS	-	2+	1+	4+	4+	2+
19	POS	3+	3+	-	2+	-	-
20	POS	2+	±	-	±	-	-

Test Date 19-Jul-2023

Test Site RL

Kit Part Code NA

Kit Lot No. 410791

Kit Exp. Date 30-Apr-2024

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

RL = Reference Lab; NA = Not Available

NEG = Negative; POS = Positive; 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.