

AccuSet™ HCV Verification Panel 1

0810-0325 / Batch #10670480

OVERVIEW

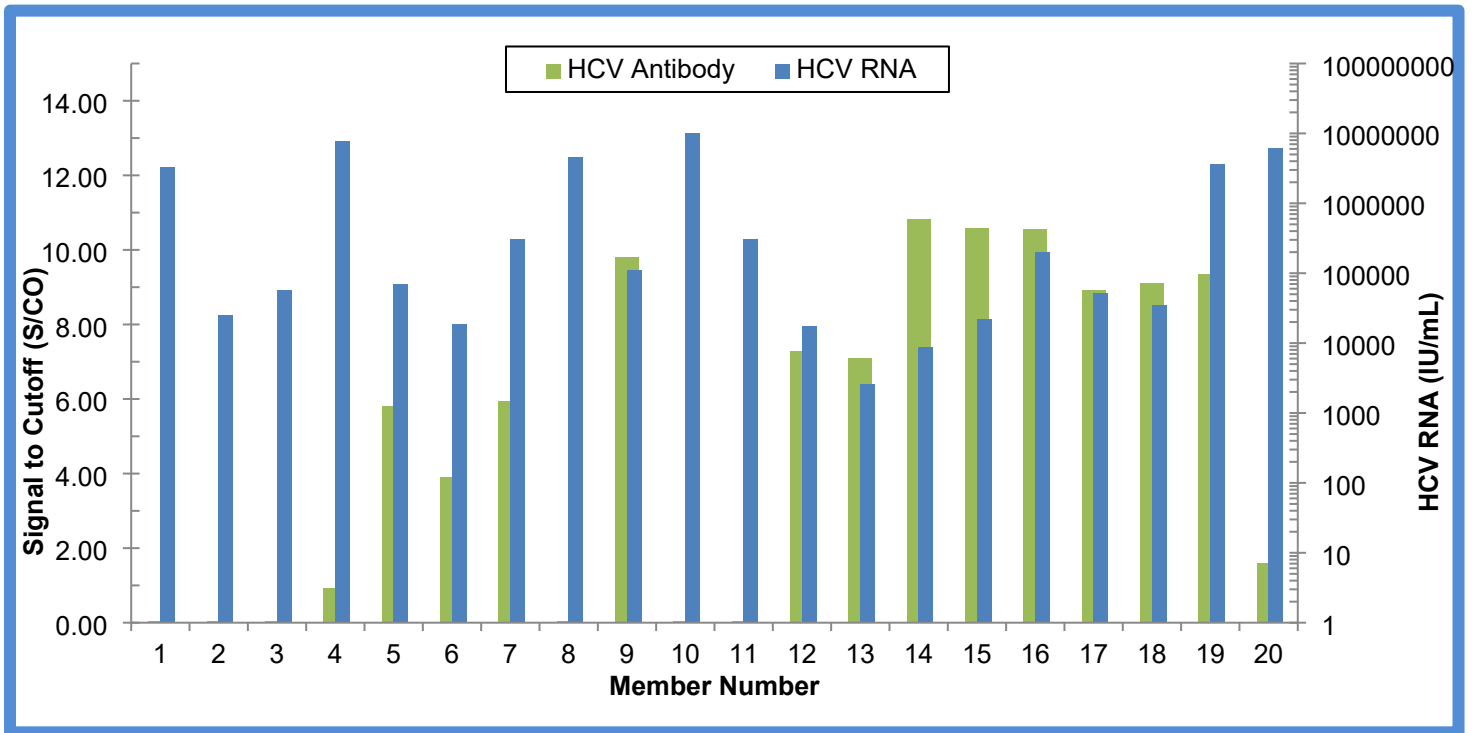
AccuSet™ HCV Verification Panel 1, 0810-0325 / Batch #10670480, is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL per vial). Panel members represent bleeds from multiple individuals positive for HCV. Each sample represents a single collection 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.

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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

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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

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

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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.