

AccuSet[™] HCV Verification Panel 2

0810-0304 / Batch #10670482

OVERVIEW

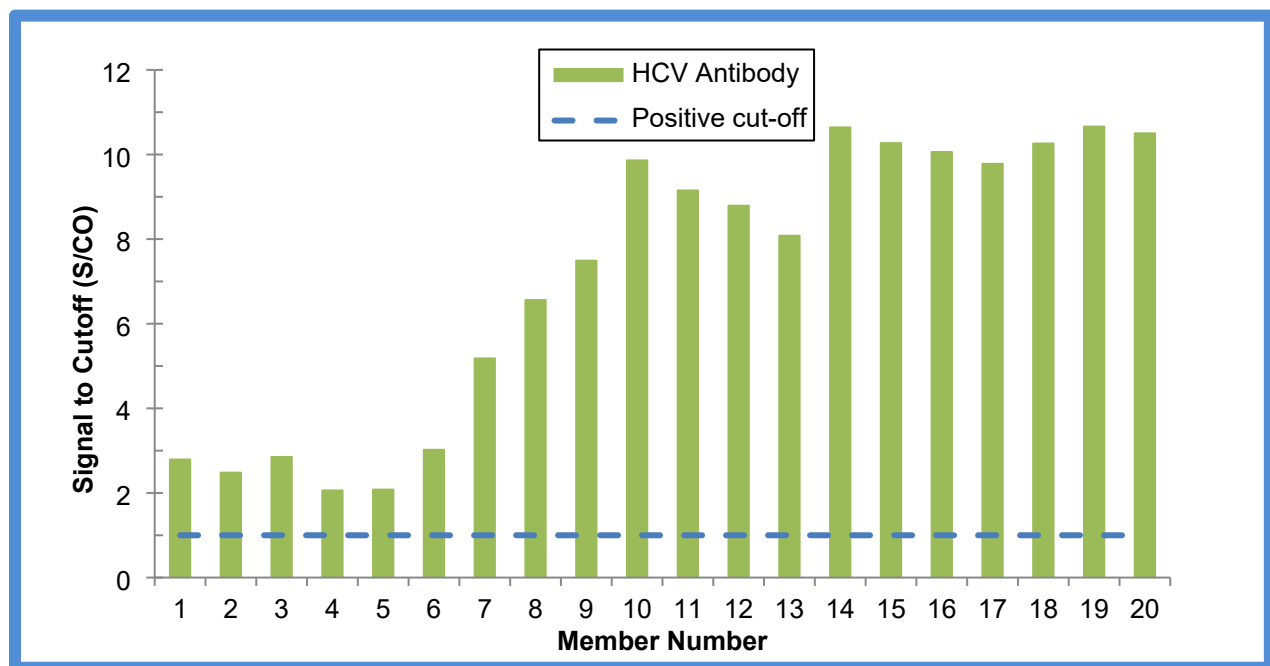
AccuSet[™] HCV Verification Panel 2, 0810-0304 / Batch #10670482, is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for HCV. Each sample represents a single collection 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 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 Abbott Alinity s (Anti-HCV) test method.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9115962	N-19538-043	05-May-2000
02	9242321	NA	18-Aug-2009
03	BM217249	0800270029	19-Jan-2007
04	9219994	6010582914	28-Sep-2007
05	9145128	24048445	19-May-2002
06	9146125	27042822	27-Nov-2002
07	9143706	23042803	16-Jul-2002
08	BM216787	0010932285	30-Aug-2006
09	9144479	23043712	24-Jul-2002
10	BM217193	0331067518	15-Dec-2006
11	BM202058	N05904520	12-Mar-2003
12	9154287	27056005	20-Jul-2003
13	9144480	23042776	16-Jul-2002
14	9146116	27036813	03-Sep-2002
15	9147502	27044317	20-Dec-2002
16	9146115	27040848	30-Oct-2002
17	9146118	27040795	29-Oct-2002
18	9147493	27044102	18-Dec-2002
19	9146120	27039326	09-Oct-2002
20	9147492	27044050	17-Dec-2002

NA = Not Available

AccuSet™ HCV

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HCV Antibody and HCV Antigen¹

Panel Member	Abbott ARCHITECT Anti-HCV (S/CO)	Abbott Alinity s Anti-HCV (S/CO)	Roche cobas® Elecsys Anti-HCV II (COI)	Abbott ARCHITECT HCV Ag (fmol/L)
01	3.97	2.79	199.95	0.00
02	3.07	2.48	51.07	0.00
03	3.68	2.85	117.35	0.00
04	3.25	2.06	84.74	0.00
05	3.47	2.08	107.95	0.00
06	5.26	3.02	28.73	145.67
07	7.24	5.18	184.50	0.00
08	9.23	6.56	145.80	111.65
09	10.41	7.49	255.05	0.00
10	10.89	9.86	39.09	2919.98
11	10.71	9.15	32.23	10.61
12	11.17	8.79	110.50	0.00
13	11.96	8.08	84.35	0.00
14	13.02	10.64	29.84	3031.94
15	11.00	10.27	30.01	9819.37
16	14.22	10.06	46.72	190.39
17	13.53	9.78	40.00	290.05
18	15.02	10.26	40.87	12.40
19	14.52	10.66	25.54	43.04
20	14.96	10.50	14.31	0.00
Test Date	11-Jul-2023	07-Jul-2023	01-Aug-2023	19-Jul-2023
Test Site	LGC	RL	RL	RL
Kit Part Code	1L79	NA	NA	NA
Kit Lot No.	50482BE00	50274BE00	NA	51301LP76
Kit Exp. Date	28-Jan-2024	09-Feb-2024	NA	02-Mar-2024

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

AccuSet™ HCV

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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	POS	1+	1+	-	2+	-	-
02	POS	2+	1+	-	2+	-	-
03	POS	1+	1+	<u>±</u>	1+	-	-
04	IND	-	-	-	1+	-	-
05	POS	-	-	-	1+	1+	-
06	POS	4+	2+	-	-	2+	3+
07	POS	1+	1+	-	2+	1+	-
08	POS	2+	2+	-	2+	-	1+
09	POS	4+	1+	-	3+	2+	1+
10	POS	2+	2+	2+	4+	-	-
11	POS	3+	2+	1+	4+	4+	4+
12	POS	3+	2+	-	3+	1+	-
13	POS	-	-	-	3+	3+	-
14	POS	3+	2+	1+	4+	4+	4+
15	POS	3+	2+	1+	4+	-	-
16	POS	3+	3+	3+	4+	3+	1+
17	POS	1+	2+	1+	4+	1+	-
18	POS	4+	4+	2+	4+	2+	2+
19	POS	3+	3+	2+	4+	2+	3+
20	POS	4+	2+	-	4+	4+	3+

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

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.