

AccuSet™ HCV Low Titer Performance Panel

0810-0372 / Batch #10754860

OVERVIEW

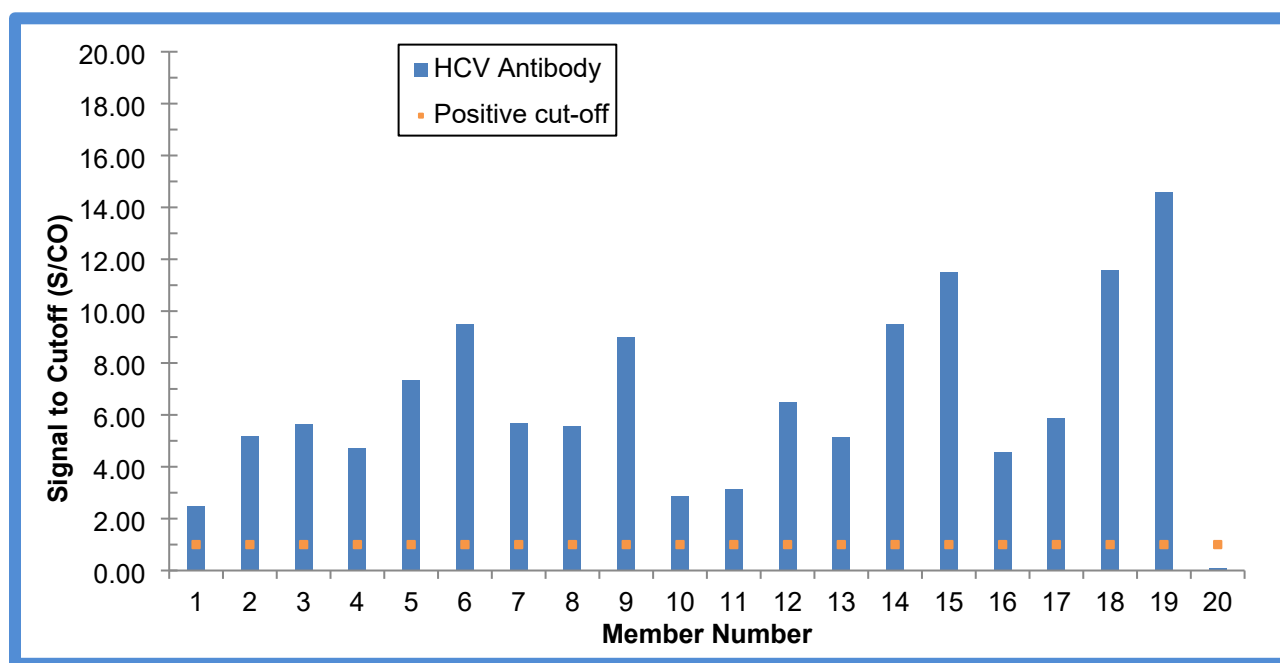
AccuSet™ HCV Low Titer Performance Panel, 0810-0372 / Batch #10754860 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HCV. Each sample represents 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 antibody reactivity which approach the sensitivity limits for several anti-HCV test methods. One sample is included as a non-reactive sample and is negative for all HCV 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 anti-HCV; all were found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

AccuSet™ HCV Low Titer Performance Panel



This graph demonstrates reactivity amongst panel members from the Abbott ARCHITECT (Anti-HCV) test method.

AccuSet™ HCV
Low Titer Performance Panel
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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	10481644	BD428653	30-Oct-2019
02	9239294	BD110242	18-Jun-1999
03	10471419	BD423911	1-Oct-2019
04	9239271	BD110230	9-Dec-1999
05	9251719	BD110854	7-Jan-2011
06	9251720	BD110854	10-Jan-2011
07	9251954	BD110877	29-Mar-2011
08	9251958	BD110877	31-Mar-2011
09	10456795	BD417501	13-Aug-2019
10	9252122	BD110914	5-Nov-2010
11	9252124	BD110915	13-Nov-2010
12	9140904	NA	NA
13	9140905	NA	NA
14	9115979	BD110585	3-Nov-1999
15	10481827	BD428662	13-Nov-2019
16	9252123	BD110914	3-Nov-2010
17	10000534	NA	NA
18	10496676	BD436234	27-Nov-2019
19	10418773	BD406221	28-Oct-2018
20	10000765	NA	NA

NA = Not Available

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HCV RNA, HCV Antigen, HCV Antibody

Panel Member	Roche cobas® 6800/8800 HCV RNA ¹ (IU/mL)	Abbott ARCHITECT HCV Ag ¹ (fmol/L)	OraSure OraQuick® HCV Rapid Antibody Test ²
01	TND	0.00	NEG
02	TND	0.00	POS
03	1.37E+07	1585.10	POS
04	TND	0.00	POS
05	2.96E+02	2.11	POS
06	8.02E+03	73.29	POS
07	TND	0.00	POS
08	TND	0.00	POS
09	2.70E+05	371.48	POS
10	TND	0.00	POS
11	TND	0.00	POS
12	TND	0.00	POS
13	TND	0.00	POS
14	TND	0.00	POS
15	3.22E+06	3277.35	POS
16	TND	0.00	POS
17	TND	0.00	POS
18	7.40E+01	0.00	POS
19	1.08E+02	0.00	POS
20	TND	0.00	NEG
Test Date	21-May-2025	21-May-2025	19-May-2025
Test Site	RL	RL	LGC
Kit Part Code	NA	NA	1001-0181
Kit Lot No.	NA	73301LP84	0006722348
Kit Exp. Date	NA	02-Dec-2025	31-Jul-2026

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.

TND = Target Not Detected; LGC = LGC Clinical Diagnostics; RL = Reference Lab; NA = Not Available

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HCV Antibody¹

Panel Member	Abbott ARCHITECT Anti-HCV (S/CO)	Abbott Alinity s Anti-HCV II (S/CO)	Roche cobas® Elecsys Anti-HCV II (COI)	DiaSorin LIAISON® XL MUREX HCV IgG Ab (S/CO)
01	2.48	0.03	0.06	0.76, 0.80*
02	5.19	59.93	214.95	3.55
03	5.66	25.75	246.30	1.65
04	4.71	42.06	284.30	2.80
05	7.33	22.95	251.10	5.10
06	9.50	22.80	211.90	5.90
07	5.70	146.37	164.40	2.80
08	5.59	144.37	172.55	2.90
09	9.02	29.63	191.50	5.35
10	2.88	118.28	157.35	2.10
11	3.14	91.51	123.40	2.00
12	6.49	142.60	214.65	4.90
13	5.14	56.01	166.70	3.95
14	9.52	113.30	218.60	6.95
15	11.52	22.64	146.75	7.55
16	4.56	129.87	204.45	3.25
17	5.89	130.87	166.00	4.85
18	11.57	21.62	51.37	7.90
19	14.59	91.28	54.82	10.00
20	0.08	0.12	0.07	0.01
Test Date	14-May-2025	15-May-2025	27-May-2025	14-May-2025
Test Site	LGC	RL	RL	LGC
Kit Part Code	1L79	NA	NA	318240
Kit Lot No.	68338BE00	72137BE00	823039	279037
Kit Exp. Date	26-Jul-2025	10-Feb-2026	31-Jul-2025	23-Oct-2025

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

*Result in gray zone. Interpretation variability; individual replicates reported.

LGC = LGC Clinical Diagnostics; RL = Reference Lab; NA = Not Available

AccuSet™ HCV

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HCV Confirmatory Assay¹

INNOGENETICS® INNO-LIA™ HCV Score

Band Results

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

Test Date 21-May-2025

Test Site RL

Kit Part Code NA

Kit Lot No. 291838

Kit Exp. Date 30-Sep-2025

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.