

AccuSet™ HCV Low Titer Performance Panel

0810-0256 / Batch #10427870

OVERVIEW

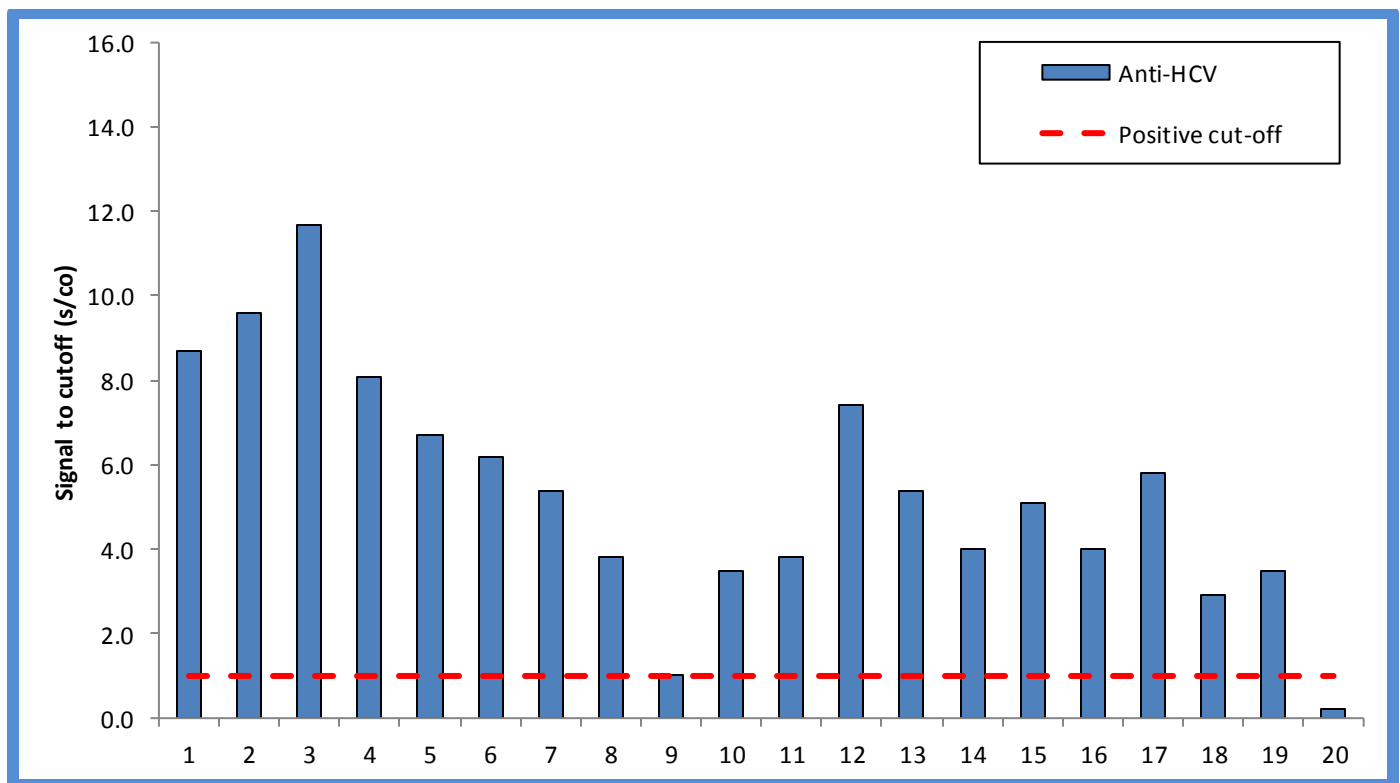
AccuSet™ HCV Low Titer Performance Panel 0810-0256 / Batch #10427870 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HCV. Each sample represents a 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. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and 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 HCV antibody reactivity amongst panel members utilizing test results from the Abbott ARCHITECT test method.

AccuSet™ HCV Low Titer Performance Panel

0810-0256 / Batch #10427870

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	10395933	BD397208	04-Dec-2018
02	10395934	BD397208	06-Dec-2018
03	9239417	BD107565	29-Jan-2009
04	9242974	BD110072	12-Oct-2009
05	9251719	BD110854	07-Jan-2011
06	9251720	BD110854	10-Jan-2011
07	9251954	BD110877	29-Mar-2011
08	9251958	BD110877	31-Mar-2011
09	10000555	NA	NA
10	9252122	BD110914	05-Nov-2010
11	9252124	BD110915	13-Nov-2010
12	9140904	NA	NA
13	9140905	NA	NA
14	10000527	NA	NA
15	10000528	NA	NA
16	9252123	BD110914	03-Nov-2010
17	10000534	NA	NA
18	10000615	NA	NA
19	10000535	NA	NA
20	9176044	NA	15-Dec-2001

NA = Not Available

AccuSet™ HCV Low Titer Performance Panel

0810-0256 / Batch #10427870

HCV RNA, HCV Antigen and Anti-HCV

Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0 (IU/mL) ^{1,3}	Abbott ARCHITECT HCV Ag (s/co) ^{2,3}	INNO-LIA™ HCV Score Band Pattern	INNO-LIA™ HCV Score Interpretation
01	1.8E+05	197.5	C1, NS3	POS
02	2.0E+04	14.4	C1, NS3	POS
03	1.1E+02	0.0	C1, C2, NS3	POS
04	1.8E+04	3497.1	C1, NS3	POS
05	9.9E+02	0.1	NS3	IND
06	3.3E+03	7.2	NS3	IND
07	TND	0.0	NS3	IND
08	TND	0.0	NS3	IND
09	TND	0.0	C1, NS3⁶, NS4⁶	POS
10	TND	0.0	C1, C2, NS3, NS4	POS
11	TND	0.0	NS3, NS4	POS
12	TND	0.0	C1, C2, NS3, NS4⁶	POS
13	TND	0.0	NS3, NS4	POS
14	NT ⁴	0.0	NS3	IND
15	TND ⁵	0.0	NS3	IND
16	TND	0.0	C1, C2, NS3, NS4	POS
17	TND	0.0	C1, C2⁶, NS3	POS
18	TND	0.0	NS3, NS4	POS
19	TND	0.0	NS3, NS4	POS
20	TND	0.0	No bands detected	NEG
Test Date	09-Jul-2019	29-Jul-2019	29-Jul-2019	
Test Site	RL	RL	RL	
Kit Part Code	NA	NA	NA	
Kit Lot No.	E21568	02301LP53	405884	
Kit Exp. Date	31-May-2020	10-Jan-2020	31-Jan-2020	

¹Results are reported as International Units per mL (IU/mL); positive/reactive results are noted in bold red.

²Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

³Results are reported as the mean result of duplicate testing.

⁴Due to unknown sample interference, Member #14 was unable to be quantified for HCV RNA.

⁵Member #15 was only tested in one replicate for HCV RNA on 19-Jul-2019.

⁶Faint bands.

TND = Target not detected; NT = Not tested

POS = Positive; NEG = Negative; IND = Indeterminate

NA = Not available

RL = Reference Lab

AccuSet™ HCV Low Titer Performance Panel

0810-0256 / Batch #10427870

Anti-HCV

Panel Member	Abbott ARCHITECT Anti-HCV (s/co) ^{1,2}	Abbott PRISM HCV (s/co) ^{1,2}	DiaSorin LIAISON® XL MUREX HCV Ab (s/co) ^{1,2}	OraSure OraQuick® HCV Rapid Antibody Test Result
01	8.7	3.5	6.9	POS
02	9.6	3.5	7.8	POS
03	11.7	4.7	9.8	POS
04	8.1	3.4	7.1	POS
05	6.7	2.9	6.2	POS
06	6.2	3.2	5.6	POS
07	5.4	1.9	4.2	POS
08	3.8	2.1	2.7	POS
09	1.0 ⁴	0.7	3.3	NEG
10	3.5	1.9	4.2	POS
11	3.8	1.6	3.7	POS
12	7.4	3.4	9.4	POS
13	5.4	2.4	5.4	POS
14	4.0	NT ³	0.9	NEG
15	5.1	2.2	1.4	NEG
16	4.0	2.0	4.6	POS
17	5.8	2.2	7.0	POS
18	2.9	1.3	3.0	POS
19	3.5	2.1	3.8	POS
20	0.2	0.4	0.1	NEG
Test Date	01-Jul-2019	02-Jul-2019 ⁵	08-Jul-2019	28-Jun-2019
Test Site	SC	RL	RL	SC
Kit Part Code	1L79	NA	310240	1001-0181
Kit Lot No.	94242LI00	03109M700	135032A	0006671855
Kit Exp. Date	23-Sep-2019	17-Feb-2020	22-Sep-2019	31-Oct-2020

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

³Due to unknown sample interference, Member #14 was unable to be tested for anti-HCV.

⁴Results are reported in the assay's gray / equivocal range.

⁵Panel Members 6, 7, and 8 of the Abbott PRISM HCV were tested on 10-Jul-2019.

NT = Not tested

POS = Positive; NEG = Negative

NA = Not available

RL = Reference Lab; SC = SeraCare

AccuSet™ HCV Low Titer Performance Panel

0810-0256 / Batch #10427870

Anti-HCV

Panel Member	ORTHO® HCV Version 3.0 ELISA Test System (s/co) ^{1,3}	Ortho VITROS® Anti-HCV (s/co) ^{1,3}	Roche Elecys Anti-HCV (s/co) ^{1,3}	Siemens ADVIA Centaur® HCV (Index) ^{2,3}
01	6.1	6.1	80.7	>11.0
02	5.9, ≥6.4⁴	6.6	82.8	>11.0
03	≥6.4⁴	19.7	47.4	>11.0
04	≥6.4⁴	7.8	78.6	>11.0
05	4.0	2.4	138.6	>11.0
06	3.0	1.9	159.6	9.8
07	6.1	5.5	127.7	7.0
08	3.8	3.1	97.9	3.6
09	1.4	6.3	18.2	1.1
10	4.6	9.7	147.7	4.1
11	3.7	3.7	116.2	4.2
12	≥6.4⁴	21.0	180.6	>11.0
13	5.9	7.2	113.8	10.8
14	1.9	2.1	0.0	0.5
15	3.3	3.8	0.0	0.9
16	5.3	11.0	158.8	4.7
17	≥6.4⁴	15.5	106.6	9.5
18	4.0	3.6	63.0	2.7
19	3.8	4.0	65.6	5.3
20	0.1	0.1	0.0	0.1
Test Date	01-Jul-2019	28-Jun-2019	11-Jul-2019	06-Jul-2019
Test Site	SC	RL	RL	RL
Kit Part Code	930740	NA	NA	NA
Kit Lot No.	TXE677	NA	NA	062322
Kit Exp. Date	31-Dec-2019	NA	NA	08-Jan-2020

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as an Index value (Index); positive/reactive results are noted in bold red.

³Results are reported as the mean result of duplicate testing.

⁴Off-scale results.

NA = Not available

RL = Reference Lab; SC = SeraCare

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 info@seracare.com or
by phone at 508.244.6400.