

AccuSet™ HCV Performance Panel

0810-0277 / Batch #10487837

OVERVIEW

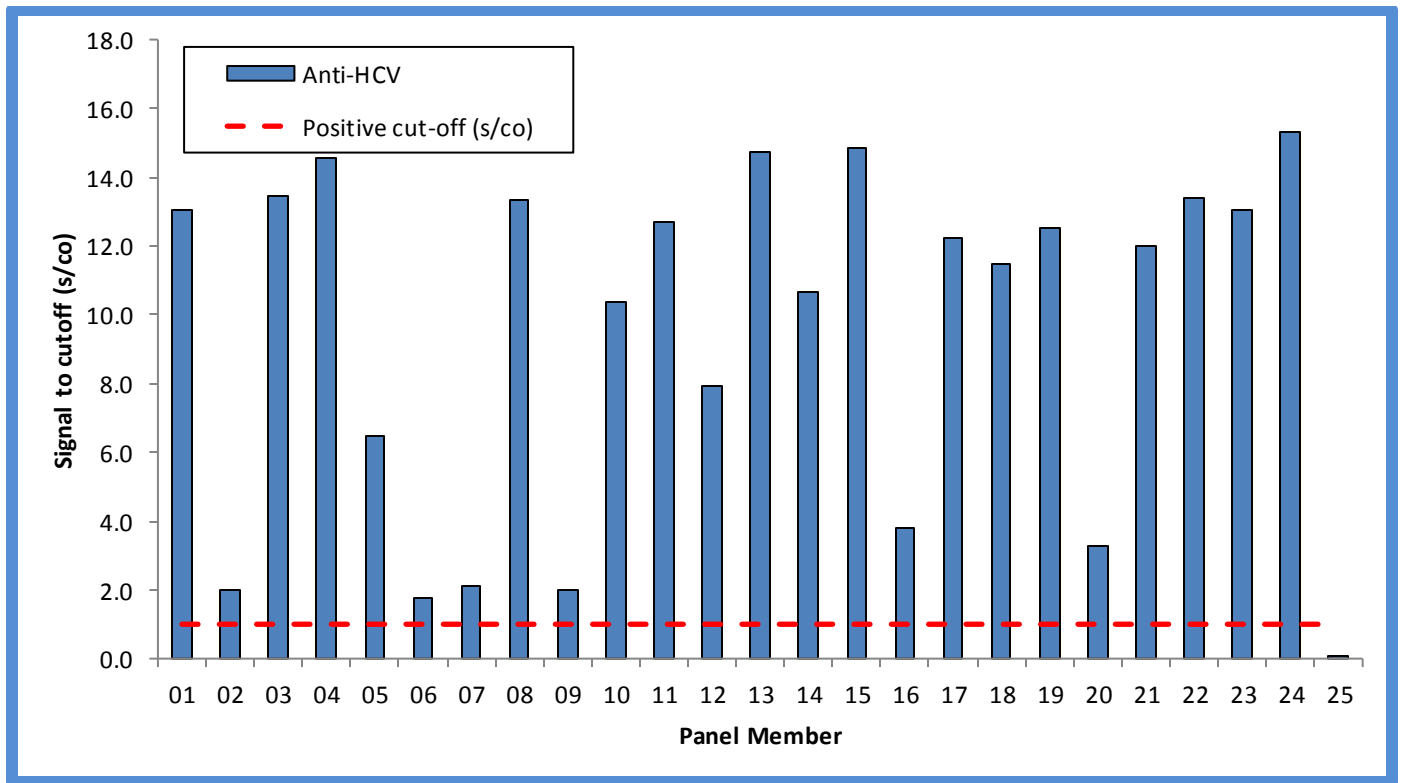
AccuSet™ HCV Performance Panel (0810-0277 / Batch #10487837) is a 25-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent collections from multiple individuals positive for antibodies to HCV. Each member represents a single collection 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 for anti-HCV test methods. Additional tests performed on HCV RNA and HCV antigen are also provided. 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 provided 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 Performance Panel



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

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9218804	BD105326	8/11/2007
02	9242322	BD110051	8/21/2009
03	10395929	BD397206	11/8/2018
04	10418772	BD406221	10/26/2018
05	BM217269	BD103806	10/25/2006
06	BM217432	BD104227	3/23/2007
07	9242333	BD110057	8/20/2009
08	10401950	BD398599	10/22/2018
09	9219995	BD105607	10/29/2007
10	10418777	BD406224	3/28/2019
11	BM217285	BD103826	12/29/2006
12	9240632	BD110015	5/19/2009
13	10401949	BD398603	12/5/2018
14	BM217376	BD104126	2/26/2007
15	10418774	BD406222	12/4/2018
16	9222534	BD105880	11/20/2007
17	10440669	BD411045	4/18/2019
18	BM217357	BD104067	1/30/2007
19	9243979	BD110090	5/22/2009
20	BM217248	BD103766	1/17/2007
21	9239418	BD107565	2/2/2009
22	10395930	BD397206	11/13/2018
23	10401951	BD398599	10/26/2018
24	9242978	BD110069	11/25/2009
25	10325214	BD357640	2/6/2014

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HCV RNA and Antigen

Panel Member	Abbott m2000 Realtime HCV (IU/mL) ^{1,3}	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0 (IU/mL) ^{1,3}	Abbott ARCHITECT HCV Ag (TV) ^{2,3}
01	1.29E+05	2.04E+05	1715.7
02	TND	TND	0.0
03	8.16E+04	1.38E+05	225.4
04	<12.00	TND	0.0
05	TND	TND	0.0
06	TND	TND	0.0
07	TND	TND	0.0
08	1.41E+05	1.42E+05	572.4
09	TND	TND	0.0
10	1.30E+06	1.14E+06	3260.3
11	4.87E+02	7.58E+02	103.6
12	4.78E+04	4.73E+04	1457.2
13	2.10E+04	2.85E+04	38.8
14	1.48E+02	1.51E+02	11.2
15	3.73E+05	6.40E+05	1254.8
16	TND	TND	0.0
17	2.42E+06	3.24E+06	4952.3
18	TND	TND	0.0
19	1.68E+06	2.57E+06	6204.5
20	TND, <12.00	TND	0.0
21	2.40E+04	3.85E+04	300.5
22	1.96E+04	3.32E+04	122.5
23	1.93E+05	2.45E+05	470.9
24	5.57E+02	5.45E+02	5.7
25	TND	TND	0.0
Test Date	04-May-2020	07-May-2020	19-May-2020
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	497772	NA	12301LP57
Kit Exp. Date	10/05/2020	NA	14-Nov-2020

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

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

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

RL = Reference Lab; NA = Not Available; TND = Target Not Detected

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HCV Antibody

Panel Member	Abbott ARCHITECT Anti-HCV (s/co) ^{1,2}	Abbott PRISM Anti-HCV (s/co) ^{1,2}	Ortho HCV Version 3.0 ELISA Test System (s/co) ^{1,2}
01	13.0	3.8	>6.3
02	2.0	1.5	2.4
03	13.4	3.6	>6.3
04	14.5	4.0	>6.3
05	6.5	2.6	>6.3
06	1.8	1.9	1.9
07	2.1	1.1	3.2
08	13.4	3.4	>6.3
09	2.0	1.0	3.1
10	10.4	3.0	6.1
11	12.7	3.3	>6.3
12	7.9	3.0	>6.3
13	14.7	3.9	>6.3
14	10.7	3.2	>6.3
15	14.8	4.1	>6.3
16	3.8	1.6	2.2
17	12.2	3.4	>6.3
18	11.5	4.4	>6.3
19	12.5	3.4	>6.3
20	3.3	1.3	3.5
21	12.0	4.0	>6.3
22	13.4	3.9	>6.3
23	13.1	3.3	>6.3
24	15.3	4.2	>6.3
25	0.1	0.1	0.0
Test Date	01-May-2020	01-May-2020	29-Apr-2020
Test Site	SC	RL	SC
Kit Part Code	1L79	NA	930740
Kit Lot No.	11004BE00	12026M700	TXE-691
Kit Exp. Date	04-Oct-2020	20-Nov-2020	08-Aug-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.

RL = Reference Lab; SC = SeraCare; NA = Not Available

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HCV Antibody

Panel Member	Ortho VITROS Anti-HCV (s/co) ^{1,2}	Roche ELECSYS Anti-HCV (s/co) ^{1,2}	Siemens ADVIA Centaur® Anti-HCV (Index) ^{2,3}
01	28.2	130.5	>11.0
02	7.1	40.1	1.3
03	12.0	81.7	>11.0
04	26.2	87.7	>11.0
05	18.0	155.0	10.6
06	1.6	0.0	0.1
07	8.7	50.9	2.0
08	13.4	76.4	>11.0
09	4.7	84.8	2.0
10	4.0	128.5	>11.0
11	14.6	72.1	>11.0
12	24.6	112.0	8.7
13	15.6	79.9	>11.0
14	23.2	103.5	>11.0
15	25.1	55.2	>11.0
16	1.7	88.9	2.5
17	29.7	104.5	>11.0
18	29.6	202.0	>11.0
19	28.2	171.0	>11.0
20	10.7	140.0	3.5
21	24.5	39.9	>11.0
22	13.3	80.8	>11.0
23	14.4	63.5	>11.0
24	28.4	63.1	>11.0
25	0.0	0.1	0.0
Test Date	05-May-2020	05-May-2020	04-May-2020
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	NA	NA	062352
Kit Exp. Date	NA	NA	18-Nov-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.

³Results are reported as an Index; positive/reactive results are noted in bold red.

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HCV Confirmatory

Panel Member	Fujirebio INNO-LIA™ HCV Score	Fujirebio INNO-LIA™ HCV Score Interpretation	OraSure Technologies OraQuick® HCV Rapid Antibody Test
01	C1, C2, NS3	POS	POS
02	C1, C2, NS3, NS4f	POS	POS ¹
03	C2f, NS3, NS4, NS5	POS	POS
04	C1, C2, E2, NS3, NS4, NS5	POS	POS
05	C1, C2, NS3, NS4, NS5f	POS	POS
06	NS3	IND	NEG
07	C1, C2, E2, NS3, NS4	POS	POS ¹
08	NS3, NS4	POS	POS
09	C1, C2f, NS3, NS4	POS	POS ¹
10	NS3	IND	POS
11	NS3	IND	POS
12	C1, C2, NS3, NS4f	POS	POS
13	NS3, NS4	POS	POS
14	C1, C2, NS3, NS4	POS	POS
15	C1, C2, NS3, NS4, NS5	POS	POS
16	NS3	IND	POS ¹
17	C1, C2, NS3	POS	POS
18	C1, C2, NS3, NS4, NS5	POS	POS
19	C1, C2, E2, NS3	POS	POS
20	C1, C2, E2, NS3	POS	POS ¹
21	C1, C2, NS3, NS4	POS	POS
22	C1f, C2, NS3, NS4, NS5	POS	POS
23	NS3, NS4	POS	POS
24	C1, C2, NS3, NS4	POS	POS
25	–	NEG	NEG
Test Date	19-May-2020		04-May-2020
Test Site	RL		SC
Kit Part Code	NA		1001-0181
Kit Lot No.	407305		0006676117
Kit Exp. Date	13-Dec-2020		30-Jun-2021

¹weak positive

POS = Positive; NEG = Negative; IND = Indeterminate; f = faint
 RL = Reference Lab; SC = SeraCare; NA = Not Available

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.