

AccuSet™ Anti-Hepatitis A Virus (HAV) Mixed Titer Performance Panel

0820-0443 / Batch #10536946

OVERVIEW

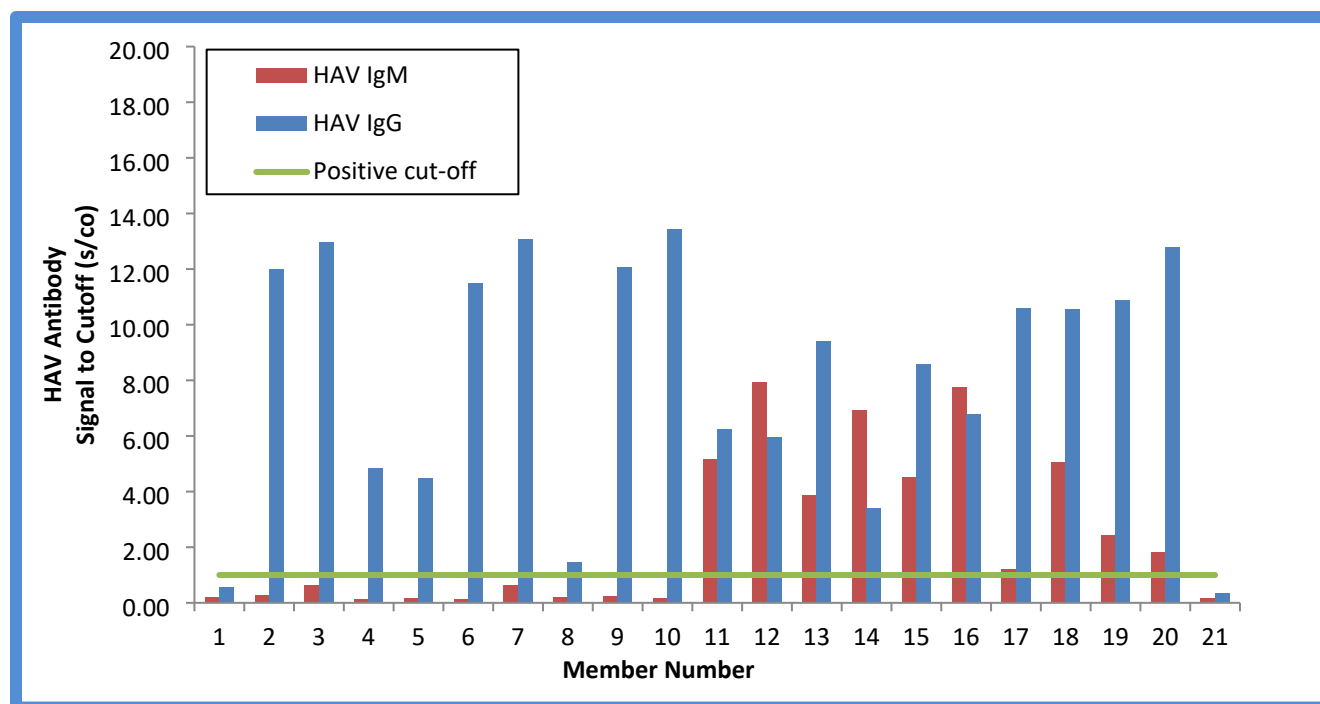
AccuSet™ anti-HAV Mixed Titer Performance Panel 0820-0443 / Batch #10536946 is a 21-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent units collected from multiple individuals positive for antibodies to HAV. Each sample represents a single collection event. No preservatives were added.

Test results from commercially available HAV 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-HAV test methods. One sample is included as a non-reactive sample and is negative for all HAV 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 Hepatitis A virus; all were found negative for HBsAg, anti-HIV-1/2 and anti-HCV. This does not ensure the absence of these or other human pathogens.

AccuSet™ anti-HAV Mixed Titer Performance Panel



This graph demonstrates the relative titer among panel members with the Abbott ARCHITECT HAV IgG and IgM test methods.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Collection Date
01*	9220032	BD105632	17-Nov-2007
02*	9205974	BD110322	27-Dec-2005
03*	9250341	BD110927	08-Sep-2010
04*	9178808	BD111241	29-Jul-2003
05*	9245375	NA	09-Apr-2010
06*	9201187	BD111322	08-Feb-2006
07*	BM204978	BD101265	20-Feb-2006
08*	9220031	BD105631	05-Nov-2007
09*	9121260	NA	27-Jul-2000
10*	9244554	NA	29-Sep-2008
11	10375420	BD387744	19-Jun-2018
12	10377384	BD390076	28-Aug-2018
13	10383842	BD392511	04-Nov-2018
14	10387645	BD392881	05-Oct-2018
15	10387651	BD392883	18-Oct-2018
16	10387859	BD392875	11-Oct-2018
17*	9246436	BD110110	17-Jun-2010
18*	9219487	NA	13-Sep-2007
19*	9245982	BD110110	30-May-2010
20*	9215222	NA	04-Apr-2007
21	10378910	BD389109	02-Jan-2018

*Panel members 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 17, 18, 19, and 20 were also utilized in SeraCare AccuSet™ HAV Performance Panel PHT202 (0820-0167).

NA = Not Available

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HAV RNA and HAV IgM

Panel Member	NGI UltraQual® 1000 HAV RNA result ¹	Abbott ARCHITECT HAVAB-M (S/CO) ²	DiaSorin LIAISON® HAV IgM (Index) ²
01	NEG	0.21	0.18
02	NEG	0.26	< 0.100
03	NEG	0.62	0.34
04	NEG	0.14	0.10
05	NEG	0.15	0.103, < 0.100
06	NEG	0.13	< 0.100
07	NEG	0.63	3.24
08	NEG	0.18	0.38
09	NEG	0.22	< 0.100
10	NEG	0.17	0.25
11	POS	5.15	> 10.00*
12	POS	7.93	> 10.00*
13	NEG	3.86	> 10.00*
14	POS	6.91	> 10.00*
15	POS	4.51	> 10.00*
16	POS	7.75	> 10.00*
17	NEG	1.22	8.68
18	POS	5.05	> 10.00*
19	POS	2.44	> 10.00*
20	NEG	1.81	6.30
21	NEG	0.15	< 0.100
Test Date	22-Jul-2021, 26-Jul-2021	19-Jul-2021	22-Jul-2021
Test Site	RL	SC	SC
Kit Part Code	NA	6L21	310210
Kit Lot No.	NA	24609BE00	112089
Kit Exp. Date	NA	26-Jan-2022	01-Feb-2022

¹Results are reported as the result of singlicate testing and positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing and positive/reactive results are noted in bold red.

*Result is off-scale.

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

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HAV IgM

Panel Member	Ortho VITROS Anti-HAV IgM (S/CO) ¹	Roche cobas® Elecsys Anti- HAV IgM (COI) ¹	Siemens ADVIA Centaur® HAV IgM (S/CO) ¹
01	0.04	0.33	0.10
02	0.07	0.25	< 0.02
03	0.09	0.30	0.23
04	0.02	0.26	< 0.02
05	0.04	0.29	0.31
06	0.01	0.25	< 0.02
07	1.28	0.99 ²	2.86
08	0.05	0.38	0.22
09	0.02	0.24	< 0.02
10	0.03	0.27	0.12
11	4.92	9.01	4.36
12	6.01	14.42	6.03
13	6.01	8.54	6.08
14	6.18	15.29	> 7.00*
15	5.21	9.84	6.47
16	7.12	16.59	> 7.00*
17	3.95	2.51	4.36
18	6.66	11.74	> 7.00*
19	5.16	5.59	6.16
20	3.03	3.61	2.93
21	0.02	0.25	0.02, < 0.02
Test Date	21-Jul-2021	21-Jul-2021	21-Jul-2021
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	5510	525763	196
Kit Exp. Date	12-Apr-2022	31-Oct-2021	25-May-2023

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

²Result is interpreted as grey/indeterminate.

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HAV IgG and HAV Total

Panel Member	Abbott ARCHITECT HAVAB-G (S/CO) ¹	Siemens ADVIA Centaur® HAV Total (Index) ¹	Ortho VITROS Anti-HAV Total (S/CO) ¹
01	0.56	0.83	0.57
02	11.98	> 5.00*	0.10
03	12.97	> 5.00*	0.08
04	4.83	4.35	0.31
05	4.46	> 5.00*	0.21
06	11.48	> 5.00*	0.09
07	13.07	> 5.00*	0.08
08	1.47	1.05	0.68
09	12.05	> 5.00*	0.09
10	13.42	> 5.00*	0.09
11	6.25	> 5.00*	0.09
12	5.95	> 5.00*	0.09
13	9.40	> 5.00*	0.08
14	3.40	> 5.00*	0.08
15	8.56	> 5.00*	0.08
16	6.78	> 5.00*	0.09
17	10.58	> 5.00*	0.09
18	10.55	> 5.00*	0.09
19	10.88	> 5.00*	0.09
20	12.77	> 5.00*	0.08
21	0.35	0.39	1.90
Test Date	19-Jul-2021	21-Jul-2021	21-Jul-2021
Test Site	SC	RL	RL
Kit Part Code	6L27	NA	NA
Kit Lot No.	19179BE00	156	5320
Kit Exp. Date	28-Aug-2021	22-Mar-2022	04-Oct-2021

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HAV Total			
Panel Member	DiaSorin LIAISON® anti-HAV (Index) ¹	Bio-Rad MONOLISA™ anti-HAV EIA (CO/S) ¹	Roche cobas® Elecsys Anti-HAV II (COI) ¹
01	0.15	1.20	0.27
02	0.10	44.54	0.01
03	< 0.100	44.54	0.01
04	1.92	2.99	0.31
05	1.11	4.82	0.27
06	0.23	40.47	0.01
07	< 0.100	44.96	0.01
08	0.15	1.61	0.19
09	< 0.100	29.43	0.01
10	< 0.100	36.16	0.01
11	< 0.100	32.58	0.01
12	< 0.100	31.00	0.01
13	< 0.100	32.58	0.01
14	< 0.100	39.13	0.01
15	< 0.100	40.31	0.01
16	< 0.100	37.94	0.01
17	< 0.100	46.07	0.01
18	< 0.100	40.47	0.01
19	< 0.100	33.44	0.01
20	< 0.100	44.54	0.01
21	> 2.70*	0.43	1.30
Test Date	19-Jul-2021	23-Jul-2021	21-Jul-2021
Test Site	SC	RL	RL
Kit Part Code	310200	72496	NA
Kit Lot No.	111099	893964	479978
Kit Exp. Date	14-Dec-2021	22-Sep-2021	31-Aug-2021

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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.