

AccuSet™ Anti-HBc IgM Mixed Titer Performance Panel

0805-0464 / Batch #10723568

OVERVIEW

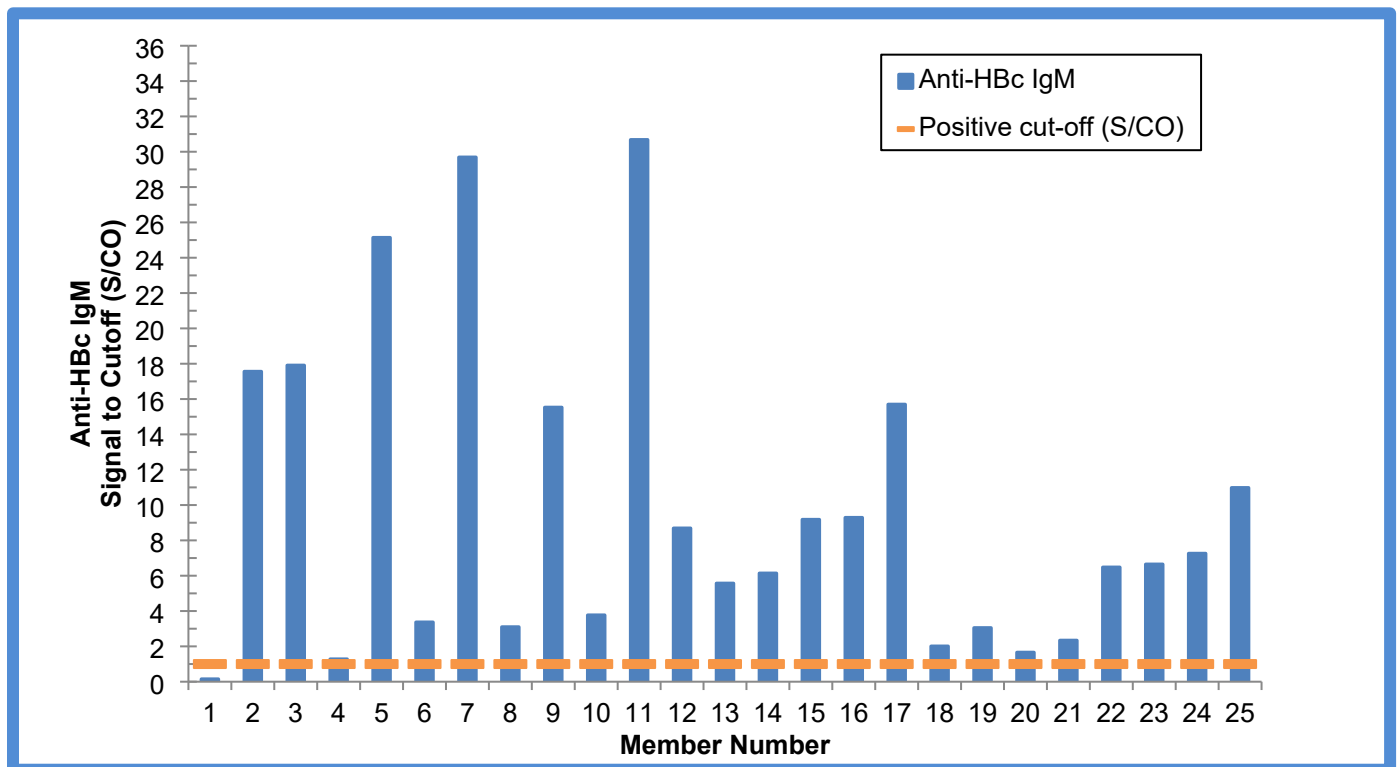
AccuSet™ Anti-HBc IgM Mixed Titer Performance Panel 0805-0464 / Batch #10723568 is a 25-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for anti-HBc IgM. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HBV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity ranging from negative to strong positive. One sample is included as a non-reactive sample and is negative for all HBV 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-HBc IgM; all were found negative. The units that make up this panel were tested and found negative for anti-HIV-1/2 and anti-HCV. This does not ensure the absence of these or other human pathogens.

Anti-HBc IgM Mixed Titer Performance Panel



This graph demonstrates panel member reactivity to the Abbott Architect Anti-HBc IgM test method.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9160899	NA	NA
02	10623135	BD500054	03-May-2022
03	10623140	BD500056	15-May-2022
04	9231135	BD106707	12-Jun-2008
05	10630434	BD500056	08-May-2022
06	9232228	BD106646	03-Sep-2008
07	9220051	NA	16-Oct-2007
08	9232724	BD106646	12-Sep-2008
09	10640989	BD509027	05-Sep-2022
10	9222135	NA	31-Dec-2008
11	10671654	BD519756	30-May-2023
12	9219955	BD200251	03-Nov-2007
13	9225608	NA	NA
14	9219956	BD200251	05-Nov-2007
15	BM217400	NA	19-Sep-2006
16	9220058	BD200256	17-Nov-2007
17	9220874	BD200258	19-Jul-2007
18	9233749	BD107175	02-Jan-2001
19	9222230	BD216138	31-Aug-2007
20	BM143501	HCM9291	02-Feb-2001
21	10000803	NA	17-Apr-1998
22	9223994	NA	22-Feb-2008
23	9226146	NA	18-Mar-2008
24	9268143	BD200004	23-May-2013
25	BM217457	NA	16-Apr-2007

NA = Not Available

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Anti-HBc IgM Assays¹

Panel Member	Abbott ARCHITECT Anti-HBc IgM (S/CO)	Abbott Alinity i Anti-HBc IgM (S/CO)	Roche Elecsys Anti-HBc IgM (COI)
01	0.15	0.15	0.16
02	17.56	19.59	11.00
03	17.91	17.57	6.80
04	1.28	1.27	0.50
05	25.14	27.53	11.51
06	3.37	3.41	2.23
07	29.69	34.83	31.67
08	3.10	3.15	2.00
09	15.53	17.79	11.31
10	3.77	3.85	2.81
11	30.68	37.32	30.19
12	8.69	8.00	4.87
13	5.57	5.59	1.80
14	6.14	6.15	4.06
15	9.18	9.96	7.65
16	9.29	9.33	7.66
17	15.70	16.97	13.46
18	2.01	1.96	0.83
19	3.05	3.05	2.96
20	1.66	1.68	0.64
21	2.34	2.51	1.56
22	6.48	6.88	5.05
23	6.65	6.67	4.68
24	7.26	7.23	4.98
25	10.98	11.66	5.20
Test Date	06-Nov-2024	06-Nov-2024	06-Nov-2024
Test Site	LGC	RL	RL
Kit Part Code	6L23	NA	NA
Kit Lot No.	62502BE00	62515BE00	768328
Kit Exp. Date	19-May-2025	19-May-2025	31-Jan-2025

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

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Anti-HBc IgM Assays¹

Panel Member	Siemens ADVIA Centaur HBc IgM (Index Value)	DiaSorin LIAISON® HBc IgM (Index Value)	Ortho VITROS Anti-HBc IgM (S/CO)
01	0.18	0.22	0.03
02	>9.00	12.80	3.37
03	>9.00	11.40	3.01
04	1.17	2.90	0.84
05	>9.00	12.20	3.34
06	3.59	4.73	1.91
07	>9.00	14.70, >15.00*	3.84
08	3.18	4.14	1.75
09	>9.00	>15.00, 14.40*	3.54
10	>9.00	8.73	2.33
11	>9.00	>15.00	3.83
12	>9.00	13.05	2.67
13	>9.00	8.77	2.28
14	>9.00	11.65	2.49
15	>9.00	11.45	3.24
16	>9.00	12.25	3.09
17	>9.00	13.85	3.61
18	4.54	5.24	1.09
19	6.33	6.40	1.74
20	1.66	2.50	0.54
21	1.89	3.06	1.50
22	>9.00	10.34	2.50
23	>9.00	9.29	2.97
24	7.89	8.21	2.79
25	>9.00	11.25	2.77
Test Date	06-Nov-2024	08-Nov-2024	06-Nov-2024
Test Site	RL	LGC	RL
Kit Part Code	NA	318140	NA
Kit Lot No.	81294211	265013	8530, 8560
Kit Exp. Date	09-Feb-2025	02-Nov-2025	25-Jan-2025, 14-Jul-2025

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*Individual replicates reported due to inability to determine an average value.

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HBsAg Assays¹

Panel Member	Abbott Alinity s HBsAg (S/CO)	Abbott Alinity i HBsAg Next Qualitative (S/CO)	Bio-Rad GS HBsAg EIA 3.0 (S/CO)
01	0.24	0.39	0.30
02	1,571.71	3,908.55	>42.55
03	0.25	0.29	0.27
04	3,734.97	3,428.15	>42.55
05	0.36	0.25	0.26
06	3,153.96	2,863.98	>42.55
07	5,225.33	6,135.02	>42.55
08	3,334.41	3,140.90	>42.55
09	6,428.15	5,999.07	>42.55
10	0.60	1.14	0.38
11	0.91	2.43	0.31
12	2.38	9.60	0.50
13	2,608.11	2,500.10	>42.55
14	4.30	14.82	1.80
15	5,942.27	5,677.25	>42.55
16	0.53	0.66	0.26
17	0.24	0.30	0.32
18	1,837.00	3,110.22	>42.55
19	5,465.15	4,837.38	>42.55
20	7,222.43	6,024.41	>42.55
21	166.71	1,017.44	41.15, >42.55*
22	1,242.25	3,384.55	>42.55
23	17.40	102.75	4.86
24	1,063.95	2,752.96	>42.55
25	0.23	0.37	0.28
Test Date	31-Oct-2024	11-Feb-2026	31-Oct-2024
Test Site	RL	RL	LGC
Kit Part Code	NA	NA	32591
Kit Lot No.	63033FZ00	81572FZ00	323UCC-05
Kit Exp. Date	16-Mar-2025	NA	31-Oct-2024

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Other HBV Assays¹

Panel Member	Roche Elecsys Anti-HBe (COI)	Diasorin LIAISON® HBsAg (Index Value)	Diasorin LIAISON® Anti-HBc (Index Value)
01	1.43	0.12	2.63, >2.70*
02	0.46	1.69	<0.10
03	1.46	0.14	0.64
04	3.34	>1,200.00	<0.10
05	1.44	0.14	0.58
06	4.02	>1,200.00	<0.10
07	0.68	1.11	0.19
08	3.62	>1,200.00	<0.10
09	1.25	0.38	0.22
10	0.38	0.11	0.15
11	0.36	0.22	<0.10
12	0.59	0.54	0.10
13	4.20	>1,200.00	<0.10
14	0.58	0.42	<0.10
15	0.11	0.35	0.22
16	0.01	0.15	<0.10
17	0.46	0.33	0.20
18	0.13	<0.10, 0.10*	<0.10
19	0.18	1.24	<0.10
20	0.21	7.53	0.29
21	1.15	4.00	<0.10
22	0.46	0.40	<0.10
23	0.15	0.17	<0.10
24	0.27	1.34	0.23
25	0.08	0.13	<0.10
Test Date	26-Nov-2024	31-Oct-2024	31-Oct-2024
Test Site	RL	LGC	LGC
Kit Part Code	NA	318150	318130
Kit Lot No.	758799	267009	263012
Kit Exp. Date	31-Aug-2025	15-Jun-2025	18-Dec-2025

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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.