

AccuSet™ Anti-HBc IgM Mixed Titer Performance Panel Modified

PHE203 (M) 0805-0216 / Batch #10048499

OVERVIEW

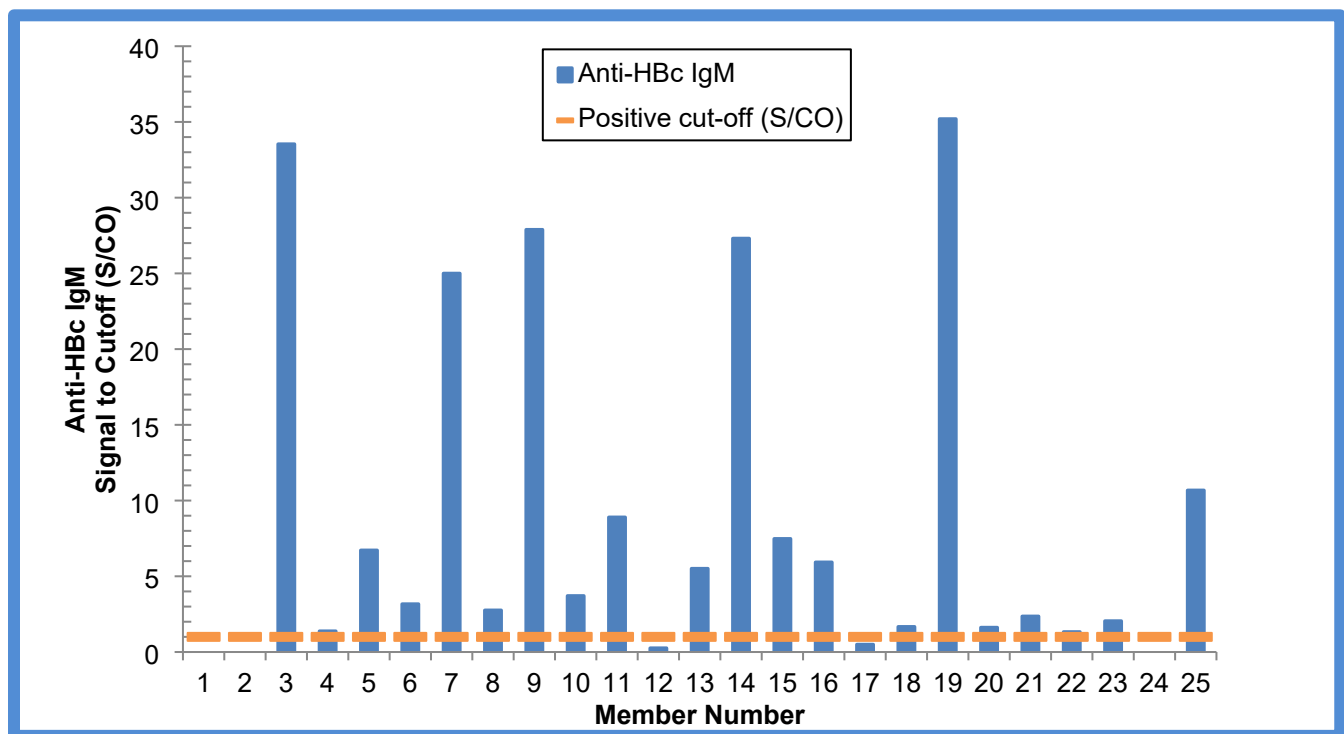
AccuSet™ Anti-HBc IgM Mixed Titer Performance Panel Modified PHE203 (M) (0805-0216) / Batch #10048499 is a 22-member validation panel of undiluted, naturally occurring plasma samples (originating from Anti-HBc Mixed Titer Performance Panel PHE203-1.0; Panel members 1, 2, and 24 from the original 25-member panel are no longer available). 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 anti-HBc IgM reactivity ranging from negative to strong positive.

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 for anti-HIV-1/2 and anti-HCV. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates panel member reactivity to the Abbott Architect (Core-M) test method. Panel members 1, 2, and 24 are no longer available and were not tested on this test method.

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Panel Member Information

Panel Member	SeraCare Batch #	Bleed Date
01*	NA	NA
02*	NA	NA
03	9218671	02-Jul-2007
04	9231135	12-Jun-2008
05	9220050	19-Nov-2007
06	9232228	03-Sep-2008
07	9220051	16-Oct-2007
08	9232724	12-Sep-2008
09	9222746	02-Jan-2008
10	9222135	31-Dec-2008
11	9225844	NA
12	9233770	29-May-1998
13	9225608	NA
14	9226147	15-Feb-2008
15	BM217400	19-Sep-2006
16	9229711	NA
17	9233790	09-Jul-2001
18	9233749	02-Jan-2001
19	BM217455	11-Dec-2006
20	BM143501	02-Feb-2001
21	10000803	17-Apr-1998
22	10000810	NA
23	BM204998	28-Jan-2006
24*	NA	NA
25	BM217457	16-Apr-2007

*Panel members 1, 2, and 24 are no longer available.
NA = Not Available

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Anti-HBc IgM Assays¹

Panel Member	Abbott Architect Core-M (S/CO)	Abbott AxSYM Core-M™ 2.0 (S/CO)	Bayer ADVIA Centaur® HBc IgM (S/CO)
01*	Not Tested	0.1	0.1
02*	Not Tested	4.9	ALR
03	33.54	5.4	ALR
04	1.38	2.1	0.9
05	6.72	3.7	ALR
06	3.17	1.8	3.7
07	25.00	5.6	ALR
08	2.76	2.0	3.0
09	27.89	5.6	ALR
10	3.71	3.1	ALR
11	8.90	4.3	ALR
12	0.26	1.2	0.5
13	5.51	3.4	8.7
14	27.31	5.2	ALR
15	7.48	4.2	5.1
16	5.93	2.8	3.2
17	0.50	2.1	0.2
18	1.67	2.7	1.8
19	35.20	5.4	ALR
20	1.62	0.8	0.7
21	2.36	1.7	0.7
22	1.33	1.5	0.9
23	2.05	1.5	1.1
24*	Not Tested	5.2	ALR
25	10.68	3.0	7.5
Test Date	22-Mar-2024	18-Dec-2008, 29-Dec-2008, 06-Mar-2009	13-Mar-2009
Test Site	SC	SC	RL
Kit Part Code	6L23	8B89-20	00504619
Kit Lot No.	59032BE00	65036M200	37559135
Kit Exp. Date	26-Jan-2025	10-Oct-2009	21-Apr-2010

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

ALR = Above the Linear Range; RL = Reference Lab; SC = SeraCare

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Anti-HBc IgM Assays¹

Panel Member	DiaSorin ETI-CORE-IGMK (HBc IgM) Plus (S/CO)	DPC IMMULITE® Anti-HBc IgM (PEI U/mL)	Ortho VITROS® Anti-HBc IgM (S/CO)
01*	0.1	<2.0	0.0
02*	10.9	>100.0	3.1
03	11.9	>100.0	3.3
04	2.0	15.2	0.6
05	9.2	>100.0	2.6
06	3.6	88.2	1.6
07	12.5	>100.0	3.3
08	3.9	98.7	1.6
09	11.8	>100.0	3.3
10	5.9	>100.0	2.2
11	11.3	>100.0	2.8
12	0.6	8.8	0.2
13	6.2	>100.0	1.9
14	11.8	>100.0	3.2
15	10.9	>100.0	2.8
16	6.1	>100.0	2.3
17	0.9	7.7	0.2
18	2.6	37.9	1.0
19	12.7	>100.0	3.3
20	0.7	57.7	0.6
21	3.3	59.6	1.4
22	2.0	32.0	1.1
23	2.1	22.4	1.1
24*	12.9	>100.0	3.2
25	7.0	>100.0	2.5
Test Date	11-Dec-2008, 16-Dec-2008, 06-Mar-2009	27-Jan-2009	05-Feb-2009, 11-Mar-2009
Test Site	SC	SC	RL
Kit Part Code	P001928	LKMC1M	6801425
Kit Lot No.	0270230B	517	6360
Kit Exp. Date	05-May-2009	31-Dec-2009	12-Oct-2009

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red. Ratios ≥ 10.0 are considered reactive for results expressed as PEI U/mL.

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Other HBV Assays¹

Panel Member	Bio-Rad GS HBsAg EIA 3.0 (S/CO)	DiaSorin LIAISON® XL Murex HBeAg Assay (Index)	DiaSorin LIAISON® XL Murex Anti-HBc Assay (Index)
01*	Not Tested	Not Tested	Not Tested
02*	Not Tested	Not Tested	Not Tested
03	>37.38	31.80	0.11
04	>37.38	>1,200.00	<0.10
05	0.36	0.11	<0.10
06	>37.38	>1,200.00	<0.10
07	>37.38	1.01	0.16
08	>37.38	1,200.00	<0.10
09	>37.38	48.25	0.11
10	0.43	0.14	0.10
11	>37.38	0.11	0.39
12	>37.38	<0.10	<0.10
13	>37.38	>1,200.00	<0.10
14	23.92	0.68, 0.72 ³	<0.10
15	>37.38	0.35	0.20
16	>37.38	0.15	<0.10
17	>37.38	<0.10, 0.11 ⁴	<0.10
18	>37.38	<0.10, 0.12 ⁴	<0.10
19	>37.38	106.50	<0.10
20	>37.38	9.18	0.22
21	34.86	4.68	<0.10
22	>37.38	>1,200.00	<0.10
23	0.92, 1.06 ²	0.67	<0.10
24*	Not tested	Not Tested	Not Tested
25	1.19	0.14	<0.10
Test Date	21-Mar-2024	21-Mar-2024	21-Mar-2024
Test Site	SC	SC	SC
Kit Part Code	32591	318150	318130
Kit Lot No.	284UCC-05	267008	263010
Kit Exp. Date	31-Aug-2024	30-Jun-2024	14-Jul-2024

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

²Interpretation variability; individual replicates reported.

³0.72 is interpreted as equivocal.

⁴Individual replicates reported, average not determined.
SC = SeraCare

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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.