

AccuSet™ HBsAg Low Titer Performance Panel

0805-0417 / Batch #10613284

OVERVIEW

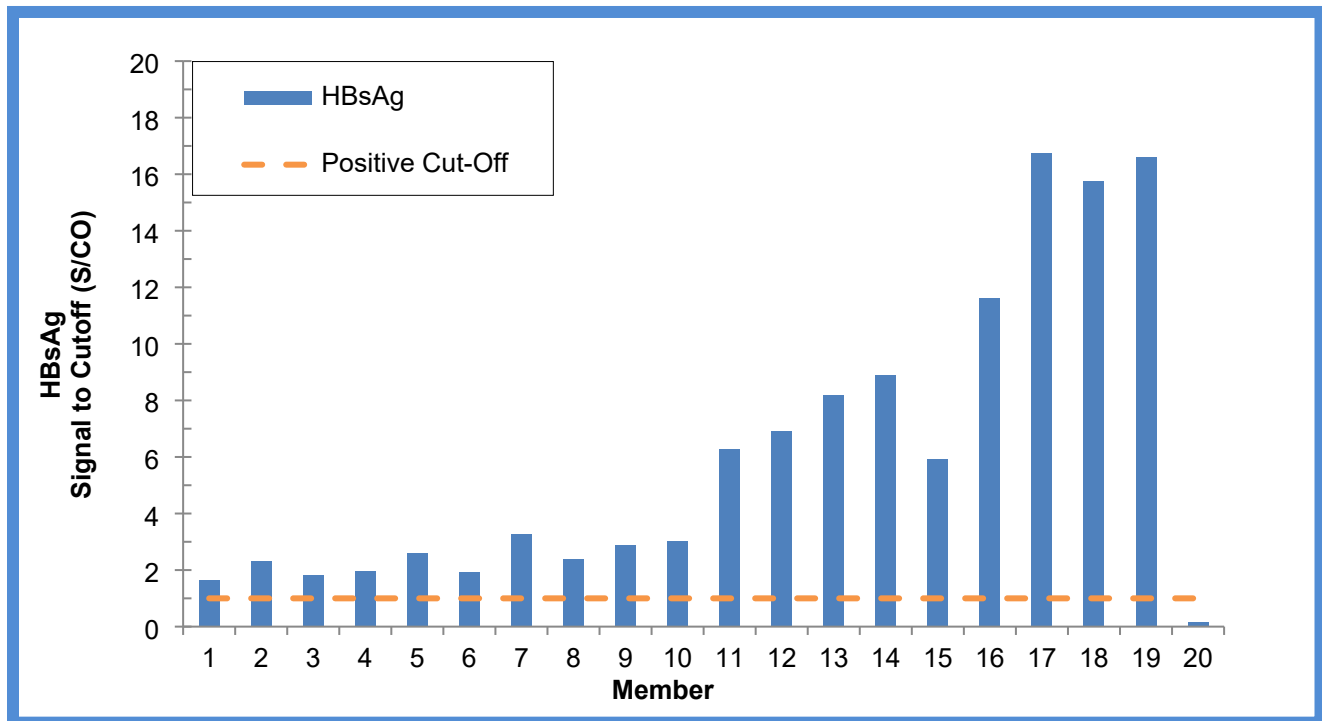
AccuSet™ HBsAg Low Titer Performance Panel 0805-0417 / Batch #10613284 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for HBsAg. Each sample represents a single collection 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 low titer reactivities for HBsAg test methods. 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 HBsAg; all were found negative for anti-HIV-1/2 and anti-HCV. This does not ensure the absence of these or other human pathogens.

AccuSet™ HBsAg Low Titer Performance Panel



This graph demonstrates reactivity amongst panel members from the Abbott ARCHITECT HBsAg Qualitative test method.

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Performance Panel
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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	BM204998	BD102189	28-Jan-2006
02	BM217629	BD104785	13-Jun-2007
03	9233734	BD107169	17-Dec-1999
04	9253283	BD110947	14-Jan-2011
05	9233739	BD107170	13-Jul-2000
06	9242009	BD110034	29-Jun-2009
07	10000540	NA	26-Jun-1996
08	10267031	BD328509	01-Aug-2016
09	10266994	BD328492	20-Oct-2016
10	10000695	BD211305	03-Nov-1997
11	10000716	BD226045	29-Jan-1998
12	BM216724	NA	NA
13	10000812	NA	18-Dec-1996
14	9145711	NA	03-Sep-1995
15	9145118	BD110654	30-Jun-2002
16	9118028	BD110506	NA
17	LSG003466	NA	NA
18	9145779	NA	26-May-1999
19	9145742	NA	30-Jul-1996
20	10310183	BD349223	31-May-2016

NA = Not Available

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HBV DNA

Panel Member	Roche COBAS® Ampliprep / COBAS® Taqman® HBV Test, v2.0 (IU/mL) ¹
01	4.47 x 10²
02	1.87 x 10³
03	1.28 x 10³
04	TND
05	1.40 x 10³
06	6.56 x 10²
07	2.44 x 10³
08	TND
09	TND
10	2.75 x 10³
11	1.72 x 10³
12	7.23 x 10³
13	1.22 x 10³
14	1.26 x 10³
15	9.45 x 10¹
16	2.06 x 10³
17	5.14 x 10⁴
18	1.42 x 10⁴
19	9.59 x 10³
20	TND
Test Date	24-May-2022
Test Site	RL
Kit Part Code	NA
Kit Lot No.	H26221
Kit Exp. Date	30-Apr-2023

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

RL = Reference Lab; NA = Not Available

TND=Target Not Detected

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HBsAg

Panel Member	Abbott ARCHITECT HBsAg Qualitative (S/CO) ¹	Abbott Alinity s HBsAg (S/CO) ¹	Roche Elecsys HBsAg II (COI) ¹	Bio-Rad GS HBsAg EIA 3.0 (S/CO) ¹	Ortho VITROS HBsAg (S/CO) ¹
01	1.65	1.40	1.24	1.1, 0.93*	0.29
02	2.31	2.15	1.64	2.10	1.51
03	1.82	1.85	1.47	1.55	0.55
04	1.98	1.90	1.53	1.07	0.18
05	2.60	2.63	1.70	1.99	0.79
06	1.93	1.72	1.45	1.64	0.60
07	3.27	3.27	1.63	2.15	0.75
08	2.40	2.56	1.73	1.33	0.22
09	2.89	3.01	2.02	1.42	0.34
10	3.04	2.33	2.09	2.22	1.06
11	6.27	5.76	3.95	4.26	2.82
12	6.91	6.95	4.11	4.89	2.54
13	8.19	7.51	5.71	8.02	4.65
14	8.91	8.20	4.93	6.73	4.19
15	5.91	5.61	2.86	4.10	2.61
16	11.63	11.00	6.34	7.75	4.70
17	16.75	15.55	12.37	11.15	7.70
18	15.77	13.34	8.46	12.29	11.05
19	16.59	14.94	9.43	12.20	12.30
20	0.15	0.21	0.36	0.32	0.06
Test Date	5-May-2022	5-May-2022	9-May-2022	10-May-2022	11-May-2022
Test Site	SC	RL	RL	SC	RL
Kit Part Code	4P53	NA	NA	32591	NA
Kit Lot No.	34193FN00	30261FN00	593640	177RCC-05	9020
Kit Exp. Date	8-Jul-2022	4-Oct-2022	30-Sep-2022	31-Jul-2022	19-Dec-2022

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

*Interpretation variability; individual replicates reported.

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HBeAg, Anti-HBe

Panel Member	DiaSorin LIAISON® XL Murex HBeAg (Index) ¹	Siemens ADVIA Centaur HBeAg (Index) ¹	Roche Elecsys Anti-HBe (COI) ¹
01	0.53	0.95, 1.1*	1.12
02	0.24	0.00	1.98
03	0.25	0.00	1.71
04	0.14	0.00	1.66
05	0.17	0.00	1.73
06	0.15, <0.10*	0.11	1.79
07	0.16	0.02	1.74
08	0.16, <0.10*	0.00	1.87
09	<0.10, 0.15*	0.00	1.93
10	0.15	0.00	1.92
11	0.22	0.00	1.83
12	0.29	0.00	1.83
13	0.21	0.00	1.82
14	0.27	0.00	1.74
15	0.20	0.00	1.90
16	0.26	0.03	1.77
17	0.39	0.10	1.48
18	0.61	0.09	1.79
19	0.43	0.04	1.74
20	0.13	0.00	1.68
Test Date	10-May-2022	09-May-2022, 18-May-2022	27-May-2022
Test Site	SC	RL	RL
Kit Part Code	318150	NA	NA
Kit Lot No.	267006	079	NA
Kit Exp. Date	2-Feb-2023	4-Aug-2023	NA

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

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Anti-HBs, Anti-HBc

Panel Member	Roche Elecsys Anti-HBs (IU/L) ¹	Abbott Alinity i Anti-HBs (mIU/mL) ¹	DiaSorin LIAISON® XL Murex Anti-HBc (Index) ¹	DiaSorin LIAISON® XL Murex HBc IgM (Index) ¹
01	<3.50	0.17	<0.10	2.91
02	<3.50	0.28	>2.70	0.18
03	<3.50	0.43	>2.70	<0.10
04	<3.50	0.38	>2.70	<0.10
05	<3.50	0.27	>2.70	<0.10
06	<3.50	0.40	2.28	<0.10
07	<3.50	0.17	>2.70	<0.10
08	<3.50	0.41	>2.70	0.11
09	<3.50	0.40	>2.70	0.13
10	<3.50	0.22	>2.70	<0.10
11	<3.50	0.38	>2.70	<0.10
12	<3.50	0.15	>2.70	<0.10
13	<3.50	0.28	>2.70	<0.10
14	<3.50	0.35	1.82	0.11
15	<3.50	0.25	>2.70	<0.10
16	<3.50	0.06	>2.70	<0.10
17	<3.50	0.74	>2.70	<0.10
18	<3.50	0.16	>2.70	<0.10
19	<3.50	0.41	>2.70	<0.10
20	<3.50	1.30	>2.70	0.11, <0.10*
Test Date	15-Jun-2022	17-May-2022	10-May-2022	10-May-2022
Test Site	RL	RL	SC	SC
Kit Part Code	NA	NA	318130	318140
Kit Lot No.	585568	27670FN00	263007	265008
Kit Exp. Date	31-Oct-2022	19-Jul-2022	23-Oct-2022	23-Oct-2022

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

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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.