

AccuSet™ HBsAg Low Titer Performance Panel

0805-0370 / Batch #10422498

OVERVIEW

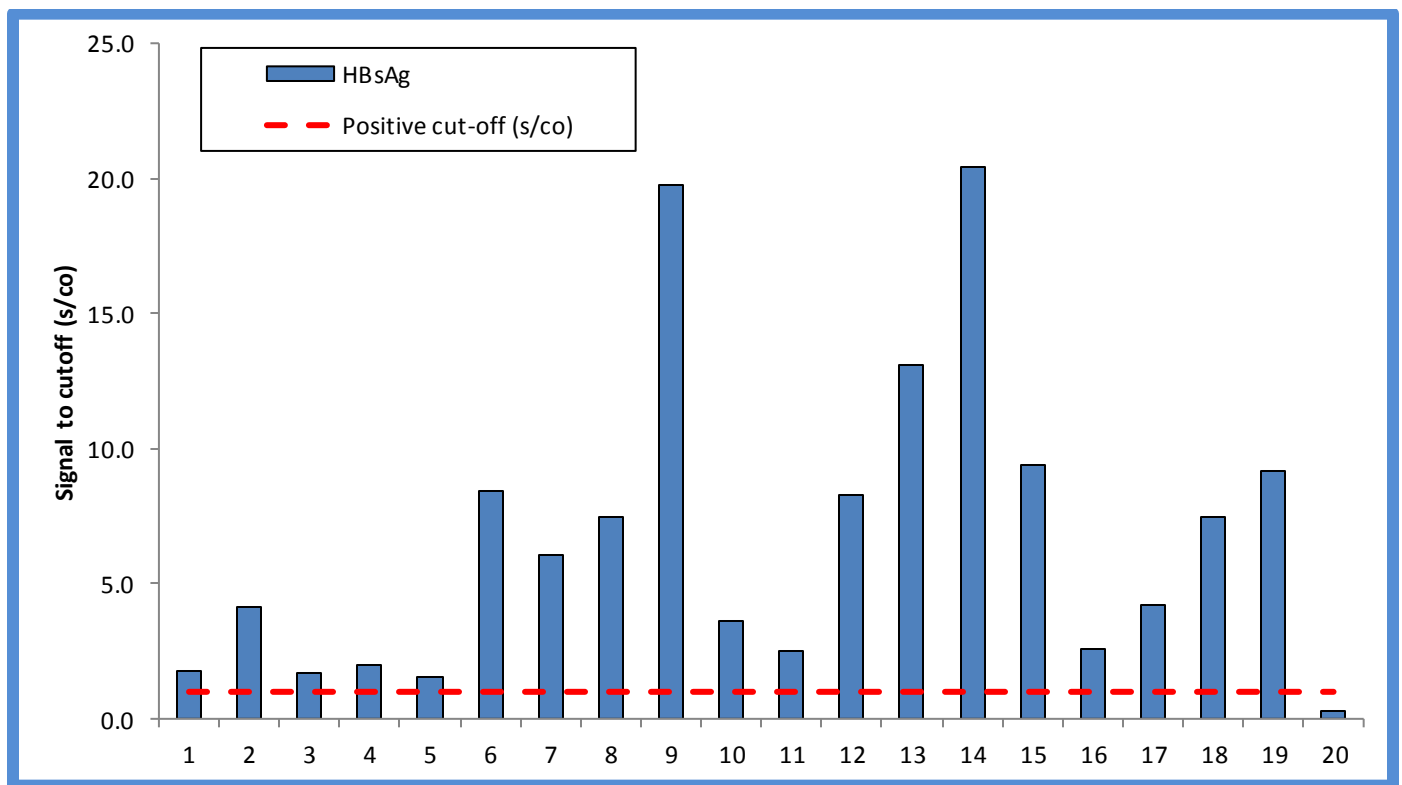
AccuSet™ HBsAg Low Titer Performance Panel 0805-0370 / Batch #10422498 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL per vial). Panel members represent bleeds from multiple individuals positive for hepatitis B antigen. Each sample represents 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 of hepatitis B antigen. One sample is included as a non-reactive sample and is negative for applicable HBV test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered 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 anti-HCV. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates reactivity amongst panel members from the GS HBsAg EIA 3.0 test system.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	10266994	BD328492	20-Oct-2016
02	10267024	BD328506	04-Jan-2017
03	10267031	BD328509	01-Aug-2016
04	10000695	BD211305	03-Nov-1997
05	9239416	BD107569	05-Feb-2009
06	10000813	NA	NA
07	10000588	NA	NA
08	10000718	BD226047	20-May-1997
09	9106123	BD110470	15-Apr-1998
10	10000701	NA	NA
11	10000719	NA	NA
12	10000794	NA	NA
13	9117818	BD110479	NA
14	9118641	BD110063	18-Apr-2000
15	10000621	NA	NA
16	BM217621	BD104769	20-Jun-2007
17	10000808	NA	NA
18	9220872	NA	31-Oct-2007
19	9220871	NA	12-Oct-2007
20	10310182	BD349222	25-May-2016

NA = Not Available

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HBV DNA, HBsAg Confirmatory

Panel Member	Roche 6800 cobas® HBV (IU/mL) ^{1,3}	Abbott PRISM HBsAg Confirmatory (s/co) ²	Abbott PRISM HBsAg Confirmatory (Neutralization %)
01	<10.0	4.8	98.17
02	<10.0	12.0	99.71
03	<10.0	5.1	96.92
04	3.0E+03	4.3	97.35
05	1.2E+03	3.8	97.93
06	4.4E+03	13.3	97.57
07	3.0E+02	8.0	96.26
08	2.2E+03	11.6	97.22
09	1.4E+04	35.9	98.94
10	2.3E+03	6.4	97.10
11	9.8E+03	5.1	95.28
12	1.7E+03	13.3	97.87
13	4.4E+04	42.8	99.23
14	6.7E+03	41.8	98.67
15	3.1E+03	16.5	98.59
16	1.5E+03	4.5	95.86
17	6.5E+01	24.3	95.41
18	<10.0	14.4	99.29
19	<10.0	18.3	99.05
20	<10.0	NA	NA
Test Date	06-Jun-2019		25-Jun-2019
Test Site	RL		RL
Kit Part Code	NA		6D16-48
Kit Lot No.	NA		95029LI00
Kit Exp. Date	NA		19-Nov-2019

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

²Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

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

NA = Not Available

RL = Reference Lab

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HBsAg

Panel Member	Abbott ARCHITECT HBsAg (s/co) ^{1,3}	Bio-Rad GS HBsAg EIA 3.0 (s/co) ^{1,3}	Ortho VITROS HBsAg (s/co) ^{1,3}	Siemens ADVIA Centaur HBsAg (INDEX) ^{2,3}	DiaSorin ETI-MAK-2 PLUS HBsAg (s/co) ^{1,3}
01	3.6	1.7	0.6	2.9	1.3
02	10.9	4.1	2.1	8.4	3.1
03	4.4	1.7	0.5	3.2	1.3
04	1.8	2.0	1.0	4.1	1.9
05	1.6	1.6	0.6	2.3	0.9 ⁴
06	10.8	8.4	5.0	19.1	3.2
07	6.6	6.0	2.7	7.5	1.8
08	8.7	7.5	4.3	13.3	3.5
09	32.7	19.7	16.8	51.7	10.1
10	5.8	3.6	1.9	7.4	1.7
11	4.8	2.5	1.5	2.5	1.2
12	11.5	8.3	5.1	15.7	4.0
13	40.1	13.1	23.9	74.7	13.4
14	41.8	20.4	20.5	61.6	11.4
15	16.4	9.4	6.4	20.5	3.5
16	2.9	2.6	0.9	5.3	1.3
17	11.8	4.2	2.4	18.5	6.3
18	10.2	7.5	4.7	15.3	5.2
19	12.7	9.2	6.1	19.0	4.7
20	0.2	0.3	0.1	0.1	0.2
Test Date	06-Jun-2019	06-Jun-2019	05-Jun-2019	05-Jun-2019	06-Jun-2019
Test Site	SC	SC	RL	RL	SC
Kit Part Code	4P54	32591	NA	NA	P001932
Kit Lot No.	96260FN00	110PCC-05	8440	180	0710700A
Kit Exp. Date	23-Sep-2019	30-Nov-2019	21-Nov-2019	31-Jan-2020	21-Aug-2019

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

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

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

⁴Results are reported within the assay's equivocal/grayzone range.

NA = Not Available

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HBsAg, HBc IgM, HBc Total

Panel Member	DiaSorin ETI-EBK PLUS HBsAg (s/co) ^{1,2}	Abbott ARCHITECT CORE-M (s/co) ^{1,2}	Abbott ARCHITECT CORE (s/co) ^{1,2}
01	0.0	0.1	0.2
02	0.0	0.2	0.4
03	0.0	0.0	0.1
04	0.1	0.0	0.2
05	0.1	0.0	0.2
06	1.7	0.1	0.4
07	0.2	0.1	0.3
08	0.1	0.0	0.3
09	0.7	0.1	0.1
10	0.2	0.1	0.1
11	0.5	0.1	0.6
12	0.1	0.1	0.3
13	3.9	0.1	0.5
14	0.8	0.1	0.2
15	0.3	0.1	0.3
16	0.3	0.2	10.0
17	0.1	1.9	9.6
18	0.4	34.9	10.4
19	0.5	35.9	10.4
20	0.1	0.1	0.1
Test Date	06-Jun-2019	05-Jun-2019	05-Jun-2019
Test Site	SC	SC	SC
Kit Part Code	P001930	6L23	6L22
Kit Lot No.	0600670A	90450LI00	96012LI00
Kit Exp. Date	31-Dec-2019	03-Oct-2019	14-Dec-2019

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.

SC = SeraCare

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.