

AccuSet™ Anti-HBc/HBs Performance Panel

0805-0341 / Batch #10383523

OVERVIEW

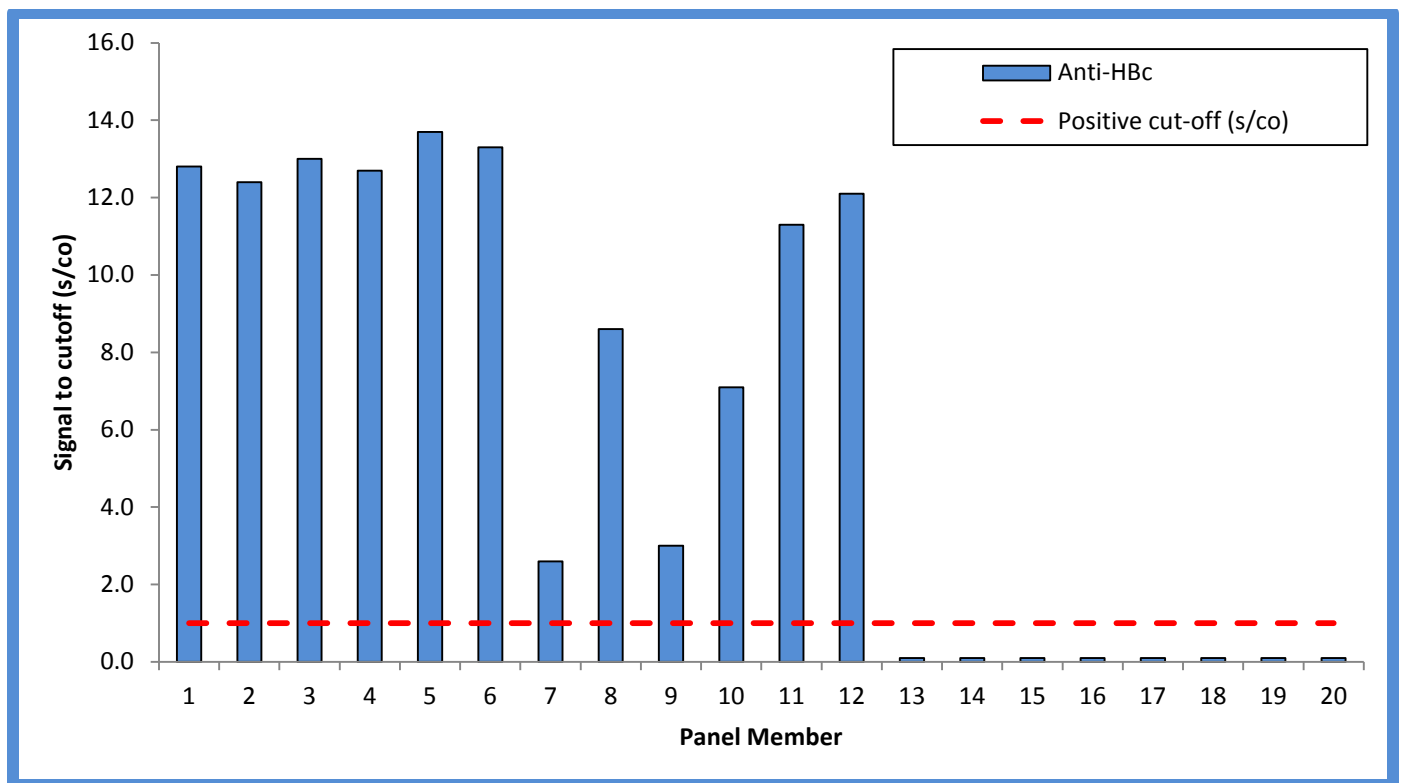
AccuSet™ Anti-HBc/HBs Performance Panel (0805-0341 / Batch #10383523) is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to hepatitis B. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available hepatitis B antibody assays are included for characterization of the panel members. This panel of human plasma samples demonstrates reactivity ranging from negative to high positive for anti-HBc and anti-HBs. One sample is included as a non-reactive sample and is negative for all hepatitis B antibody 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 for anti-HIV 1/2, HBsAg, and anti-HCV. Several members were found positive for HBsAg. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates the breadth of anti-HBc antibody reactivity amongst panel members utilizing Abbott ARCHITECT CORE assay results.

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Performance Panel
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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	10266999	BD328495	11-Jan-2016
02	10267000	BD328495	16-Jan-2016
03	10267013	BD328501	25-Sep-2015
04	10267014	BD328501	02-Oct-2015
05	10267019	BD328504	18-Apr-2016
06	10267034	BD328511	24-Jan-2016
07	10083557	BD221933	13-Nov-2014
08	10087015	BD220340	06-Sep-2013
09	10125315	BD250028	12-Mar-2014
10	10228579	BD307508	10-Apr-2016
11	10257101	BD323607	29-Jun-2016
12	10109391	BD238230	13-Dec-2013
13	10284014	BD336272	28-Nov-2016
14	10284395	BD336648	21-Nov-2016
15	10062813	BD213230	20-Aug-2013
16	10062817	BD213234	26-Jun-2012
17	10250804	BD319776	27-Jun-2015
18	10250811	BD319778	27-Aug-2015
19	10250857	BD319809	22-Dec-2016
20	10347230	BD370319	11-Oct-2017

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Anti-HBc

Panel Member	Abbott ARCHITECT CORE Anti-HBc (s/co) ^{1,4}	DiaSorin ETI-AB-COREK PLUS Anti-HBc (co/s) ^{2,4}	Ortho VITROS Anti-HBc (s/co) ^{1,4}	Roche Elecsys Anti-HBc (COI) ^{3,4}
01	12.8	>253.0	0.0	0.0
02	12.4	>253.0	0.0	0.0
03	13.0	>253.0	0.0	0.0
04	12.7	>253.0	0.0	0.0
05	13.7	>253.0	0.0	0.0
06	13.3	>253.0	0.0	0.0
07	2.6	21.1	0.4	0.1
08	8.6	>253.0	0.1	0.0
09	3.0	23.6	0.3	0.1
10	7.1	>253.0	0.0	0.0
11	11.3	>253.0	0.0	0.0
12	12.1	>253.0	0.0	0.0
13	0.1	0.2	3.2	2.4
14	0.1	0.3	2.9	2.4
15	0.1	0.4	3.1	2.4
16	0.1	0.3	2.9	2.1
17	0.1	0.4	2.7	2.3
18	0.1	0.4	3.0	2.0
19	0.1	0.3	3.1	2.4
20	0.1	0.2	2.4	2.4
Test Date	20-Nov-2018	19-Nov-2018	21-Nov-2018	07-Dec-2018
Test Site	SC	SC	RL	RL
Kit Part Code	6L22	P001927	NA	NA
Kit Lot No.	88047LI00	9910670A	NA	NA
Kit Exp. Date	26-Mar-2019	07-Mar-2019	NA	NA
Kit Regulatory Status	IVD	IVD	IVD	IVD

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

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

³Results are reported as cutoff index (COI); positive/reactive results are noted in bold red.

⁴Results are reported as the mean result of duplicate testing.

NA = Not Available

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Anti-HBs

Panel Member	Abbott ARCHITECT Anti-HBs (mIU/mL) ^{1,3}	DiaSorin ETI-AB-AUK PLUS Anti-HBs (s/co) ^{2,3}	Roche Elecsys Anti-HBs (mIU/mL) ^{1,3}	Siemens ADVIA Centaur Anti-HBs2 (mIU/mL) ^{1,3}
01	0.8	0.0	2.0	<3.1
02	1.6	0.0	2.0	<3.1
03	2.4	0.2	2.0	<3.1
04	1.1	0.2	2.0	<3.1
05	0.1	0.0	2.0	<3.1
06	0.5	0.0	2.0	<3.1
07	>1000	>19.1	>1000.0	>1000.0
08	>1000	>19.1	>1000.0	>1000.0
09	704.0	>19.1	745.0	840.9
10	348.7	14.6	380.1	548.8
11	358.7	9.2	328.3	455.6
12	>1000	18.5, >19.1	>1000.0	>1000.0
13	>1000	>19.1	>1000.0	>1000.0
14	>1000	>19.1	>1000.0	>1000.0
15	27.2	1.2	56.5	33.9
16	605.7	>19.1	695.4	983.8, >1000.0
17	387.5	15.0	514.4	736.7
18	44.7	3.0	62.5	62.7
19	102.6	6.3	140.6	146.5
20	2.2	0.1	2.9	<3.1
Test Date	20-Nov-2018	20-Nov-2018	07-Dec-2018	27-Nov-2018
Test Site	SC	SC	RL	RL
Kit Part Code	1L82	P001931	NA	NA
Kit Lot No.	87201FN00	0650460A	NA	NA
Kit Exp. Date	09-Jul-2019	31-Mar-2019	NA	NA
Kit Regulatory Status	IVD/CE	IVD	IVD	IVD/CE

¹Results are reported as milli-international units per mL (mIU/mL); positive/reactive results are noted in bold red.

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HBsAg, HBeAg

Panel Member	Abbott ARCHITECT HBsAg (s/co) ^{1,3}	Roche Elecsys HBsAg (COI) ^{2,3}	Bio-Rad GS HBsAg EIA 3.0 (s/co) ^{1,3}	Abbott ARCHITECT HBeAg (s/co) ^{1,3}	Roche Elecsys HBeAg (COI) ^{2,3}
01	4006.5	3209.0	>40.0	70.6	67.7
02	3912.1	2435.5	>40.0	54.9	78.7
03	4883.0	5667.0	>40.0	0.3	0.1
04	4957.6	5418.5	>40.0	0.3	0.1
05	5583.1	7191.5	>40.0	0.3	0.1
06	3725.6	2867.0	>40.0	0.3	0.1
07	0.2	0.4	0.3	0.3	0.1
08	0.2	0.5	0.3	0.3	0.1
09	0.3	0.4	0.3	0.3	0.1
10	0.2	0.4	0.3	0.3	0.1
11	0.2	0.5	0.3	0.3	0.1
12	0.2	0.4	0.3	0.3	0.1
13	0.2	0.5	0.2	0.3	0.1
14	0.2	0.4	0.3	0.3	0.1
15	0.2	0.4	0.3	0.3	0.1
16	0.3	0.4	0.3	0.3	0.1
17	0.2	0.5	0.3	0.3	0.1
18	0.2	0.4	0.3	0.3	0.1
19	0.2	0.5	0.2	0.3	0.1
20	0.2	0.5	0.2	0.3	0.1
Test Date	20-Nov-2018	07-Dec-2018	20-Nov-2018	17-Dec-2018	07-Dec-2018
Test Site	SC	RL	SC	RL	RL
Kit Part Code	4P54	NA	32591	NA	NA
Kit Lot No.	91069FN00	NA	171NCC-05	92369LI00	NA
Kit Exp. Date	02-Apr-2019	NA	31-Jul-2019	17-Jul-2019	NA
Kit Regulatory Status	IVD	IVD	IVD/CE	IVD/CE	IVD

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Anti-HBc IgM, Anti-HBe

Panel Member	Abbott ARCHITECT CORE-M Anti-HBc IgM (s/co) ^{1,3}	DiaSorin ETI-CORE-IgMK PLUS Anti-HBc IgM (s/co) ^{1,3}	Abbott ARCHITECT Anti-HBe (s/co) ^{1,3}	DiaSorin ETI-AB-EBK PLUS Anti-HBe (co/s) ^{2,3}
01	0.1	0.3	6.7	0.2
02	0.1	0.3	3.7	0.2
03	0.1	0.2	0.0	249.2
04	0.1	0.2	0.0	224.3
05	0.1	0.2	0.0	299.0
06	0.1	0.2	0.0	448.5
07	0.1	0.2	1.7	0.8
08	0.1	0.2	1.1	2.5
09	0.1	0.1	2.2	0.5
10	0.1	0.1	0.4	2.9
11	0.1	0.1	2.1	0.6
12	0.4	0.6	0.4	3.8
13	0.1	0.1	2.3	0.5
14	0.1	0.1	2.2	0.5
15	0.1	0.1	2.2	0.5
16	0.1	0.1	2.0	0.5
17	0.1	0.2	2.0	0.5
18	0.1	0.1	2.2	0.5
19	0.1	0.1	2.4	0.5
20	0.1	0.1	2.0	0.5
Test Date	26-Nov-2018	28-Nov-2018	17-Dec-2018	20-Nov-2018
Test Site	SC	SC	RL	SC
Kit Part Code	6L23	P001928	NA	P001929
Kit Lot No.	88529LI00	0270480A	93307LI00	0490730AA
Kit Exp. Date	09-Aug-2019	31-May-2019	21-Aug-2019	27-Mar-2019
Kit Regulatory Status	IVD	IVD	IVD / CE	IVD

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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 info@seracare.com or by phone at 508.244.6400.