

OVERVIEW

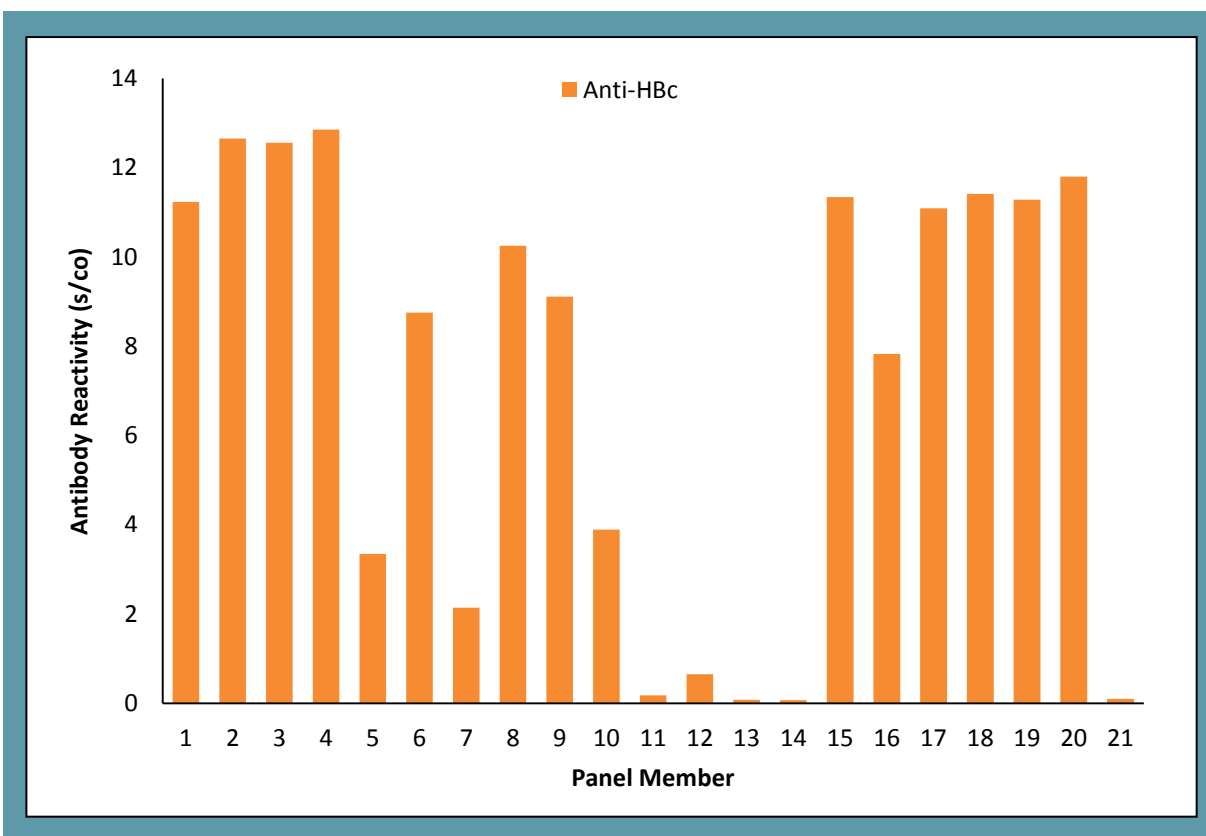
Anti-HBc/HBs Mixed Titer AccuSet™ Performance Panel (0805-0218) is a 21-member panel of undiluted, naturally occurring plasma samples. Panel members represent bleeds from multiple individuals positive for antibodies to hepatitis B core antigen (anti-HBc total) and hepatitis B surface antigen (anti-HBs). 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 provided 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 and some panel members were found positive for anti-HIV 1/2 and/or anti-HCV. This does not ensure the absence of these or other human pathogens.

Anti-HBc/HBs Mixed Titer AccuSet™ Performance Panel



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

Anti-HBc Test Methods

Panel Member	Abbott ARCHITECT® CORE (s/co) ^{1,2}	Abbott PRISM® HBV Core Antigen (s/co) ^{1,2}	DiaSorin ETI-AB-COREK PLUS (anti-HBc) (co/s) ^{2,3}	Ortho VITROS® Anti-HBc Assay ²	ORTHO® HBc ELISA Test System (s/co) ^{1,2}	Siemens ADVIA Centaur® Anti-HBc Total (mIU/mL) ^{2,4}
01	11.23*	0.02	408.00	Reactive	6.58*	>8.00
02	12.65*	0.02	233.14	Reactive	6.58*	>8.00
03	12.56*	0.04	63.47	Reactive	6.58*	>8.00
04	12.85*	0.04	408.00	Reactive	6.58*	>8.00
05	3.35	0.45	2.88	Reactive	1.51	3.30
06	8.75*	0.13	272.00	Reactive	6.58*	>8.00
07	2.14	0.74	47.69	Reactive	2.65	0.66
08	10.25*	0.11	408.00	Reactive	6.58*	>8.00
09	9.11*	0.15	229.50	Reactive	6.58*	2.87
10	3.89	0.32	226.67	Reactive	3.77	1.99
11	0.18	1.75	0.22	Non-Reactive	0.03	0.17
12	0.65	0.90	2.20	Non-Reactive	0.67	0.62
13	0.08	1.72	0.28	Non-Reactive	0.36	0.17
14	0.07	1.48	0.23	Non-Reactive	0.28	0.18
15	11.34*	0.10	408.00	Reactive	6.58*	>8.00
16	7.83*	0.15	408.00	Reactive	6.58*	>8.00
17	11.09*	0.08	408.00	Reactive	6.58*	>8.00
18	11.41*	0.09	108.80	Reactive	6.58*	>8.00
19	11.28*	0.04	204.00	Reactive	6.58*	>8.00
20	11.80*	0.05	170.00	Reactive	6.58*	>8.00
21	0.10	1.51	0.22	Non-Reactive	0.07	0.17
Test Date	02-Oct-14	01-Oct-14	03-Oct-14	01-Oct-14	30-Sep-14	01-Oct-14
Test Site	SC	RL	SC	RL	SC	RL
Kit Part Code	6L22	NA	P001927	NA	933245	NA
Kit Lot No.	40630LI00	NA	9910530A	NA	CHK578	NA
Kit Exp. Date	22-Apr-15	NA	21-Mar-15	NA	05-Apr-15	NA
Kit Regulatory	IVD	IVD	IVD	IVD	IVD	IVD

¹Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

³Results are reported as a cut-off to signal value (co/s). Positive/reactive results are noted in bold red.

⁴Result is reported in milli-international units per milliliter (mIU/mL). Positive/reactive results are noted in bold red.

*ALR = above the limit of reactivity

SC = SeraCare; RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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Anti-HBs Test Methods

Panel Member	Abbott ARCHITECT® Anti-HBs (mIU/mL) ^{1,3}	Bio-Rad MONOLISA™ Anti-HBs EIA (s/co) ^{2,3}	DiaSorin ETI-AB-AUK PLUS (anti-HBs) (s/co) ^{2,3}	Ortho VITROS® Anti-HBs Assay (s/co) ^{2,3}	Siemens ADVIA Centaur® Anti-HBs Total (mIU/mL) ^{1,3}
01	0.37	0.41	0.00	<5.00	<3.10
02	0.13	0.31	0.05	<5.00	<3.10
03	0.35	0.97 ⁴	0.08	<5.00	<3.10
04	0.37	0.40	0.01	<5.00	<3.10
05	1.18	0.34	0.09	<5.00	<3.10
06	163.59	0.88	4.90	78.50	183.57
07	225.76	3.54	9.34	180.00	341.37
08	12.72	0.69	0.61	5.50 ⁴	17.18
09	1000.00*	27.14	12.99*	>1000.00	>1000.00
10	528.86	8.65	12.99*	399.00	667.13
11	6.33	4.72	1.86	20.50	20.69
12	63.98	1.39	4.57	50.50	50.58
13	51.44	0.86	4.53	33.50	90.74
14	36.13	0.63	3.10	21.50	55.82
15	17.19	1.31	0.94 ⁴	8.00 ⁴	23.80
16	24.73	1.30	0.07	<5.00	30.06
17	9.56	0.32	0.02	<5.00	<3.10
18	0.00	0.27	0.05	<5.00	<3.10
19	3.37	0.32	0.03	<5.00	5.85
20	0.71	0.27	0.05	<5.00	<3.10
21	1.57	0.29	0.13	<5.00	<3.10
Test Date	02-Oct-14	06-Oct-14	02-Oct-14	01-Oct-14	01-Oct-14
Test Site	SC	SC	SC	RL	RL
Kit Part Code	1L82	25220	P001931	NA	NA
Kit Lot No.	37398LF00	105JEE	0650350A	NA	NA
Kit Exp. Date	21-Apr-15	24-Feb-15	31-Dec-14	NA	NA
Kit Regulatory Status	IVD/CE	IVD	IVD	IVD	IVD

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²Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red.

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

⁴Result is equivocal/grey zone.

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Other HBV Antibody Test Methods

Panel Member	Abbott ARCHITECT® HBc IgM (s/co) ^{1,2}	DiaSorin ETI-CORE-IgMK PLUS (IgM anti-HBc) (s/co) ^{1,2}	DiaSorin ETI-AB-EBK PLUS (anti-HBe) (co/s) ^{2,3}	Ortho VITROS® Anti-HBe ²
01	0.37	0.34	4.21	Reactive
02	0.49	0.70	2.05	Non-Reactive
03	0.17	0.20	1.82	Non-Reactive
04	0.07	0.16	546.00	Reactive
05	1.37	2.07	0.53	Non-Reactive
06	0.14	0.19	2.94	Reactive
07	0.12	0.12	0.62	Non-Reactive
08	0.16	0.14	0.67	Non-Reactive
09	0.37	0.38	1.87	Reactive
10	0.11	0.19	0.83	Non-Reactive
11	0.04	0.09	0.53	Non-Reactive
12	0.06	0.10	0.70	Non-Reactive
13	0.06	0.11	0.56	Non-Reactive
14	0.05	0.10	0.55	Non-Reactive
15	0.20	0.21	0.77	Non-Reactive
16	0.04	0.09	0.73	Non-Reactive
17	0.05	0.12	0.83	Non-Reactive
18	0.14	0.17	1.21	Non-Reactive
19	0.05	0.10	0.93 ⁴	Non-Reactive
20	0.13	0.20	8.08	Reactive
21	0.07	0.11	0.55	Non-Reactive
Test Date	29-Sep-14	03-Oct-14	03-Oct-14	30-Sep-14
Test Site	SC	SC	SC	RL
Kit Part Code	6L23	P001928	P001929	NA
Kit Lot No.	42374LI00	0270370A	0490550A	NA
Kit Exp. Date	16-Sep-15	31-Mar-15	31-Mar-15	NA
Kit Regulatory Status	IVD/CE	IVD	IVD	IVD

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HBsAg and HBeAg Test Methods

Panel Member	Abbott PRISM® HBsAg (s/co) ^{1,2}	Bio-Rad Genetic Systems™ HBsAg EIA 3.0 (s/co) ^{1,2}	DiaSorin ETI-EBK PLUS (HBeAg) (s/co) ^{1,2}	Ortho VITROS® HBeAg ²
01	454.01	33.33*	0.02	Non-Reactive
02	585.09	33.33*	0.21	Non-Reactive
03	845.80	33.33*	0.13	Non-Reactive
04	442.77	33.33*	0.02	Non-Reactive
05	2.30	1.76	0.02	Non-Reactive
06	0.31	0.22	0.07	Non-Reactive
07	0.37	0.22	0.02	Non-Reactive
08	0.48	0.27	0.02	Non-Reactive
09	0.29	0.21	0.02	Non-Reactive
10	0.30	0.22	0.07	Non-Reactive
11	0.54	0.23	0.06	Non-Reactive
12	0.49	0.28	0.03	Non-Reactive
13	0.28	0.20	0.02	Non-Reactive
14	0.27	0.21	0.05	Non-Reactive
15	0.38	0.26	0.03	Non-Reactive
16	0.28	0.27	0.03	Non-Reactive
17	0.28	0.27	0.02	Non-Reactive
18	0.24	0.32	0.19	Non-Reactive
19	0.26	0.21	0.04	Non-Reactive
20	0.28	0.21	0.05	Non-Reactive
21	0.25	0.26	0.03	Non-Reactive
Test Date	01-Oct-14	29-Sep-14	02-Oct-14	30-Sep-14
Test Site	RL	SC	SC	RL
Kit Part Code	NA	32591	P001930	NA
Kit Lot No.	NA	301HCC-05	0600480A	NA
Kit Exp Date	NA	30-Sep-14	31-Mar-15	NA
Kit Regulatory Status	IVD/CE	IVD	IVD	IVD

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The Package Insert for this panel in PDF form 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

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