

AccuSet™ HBsAg Mixed Titer Performance Panel Modified

0805-0314 (PHA207(M)) / Batch #10142689

OVERVIEW

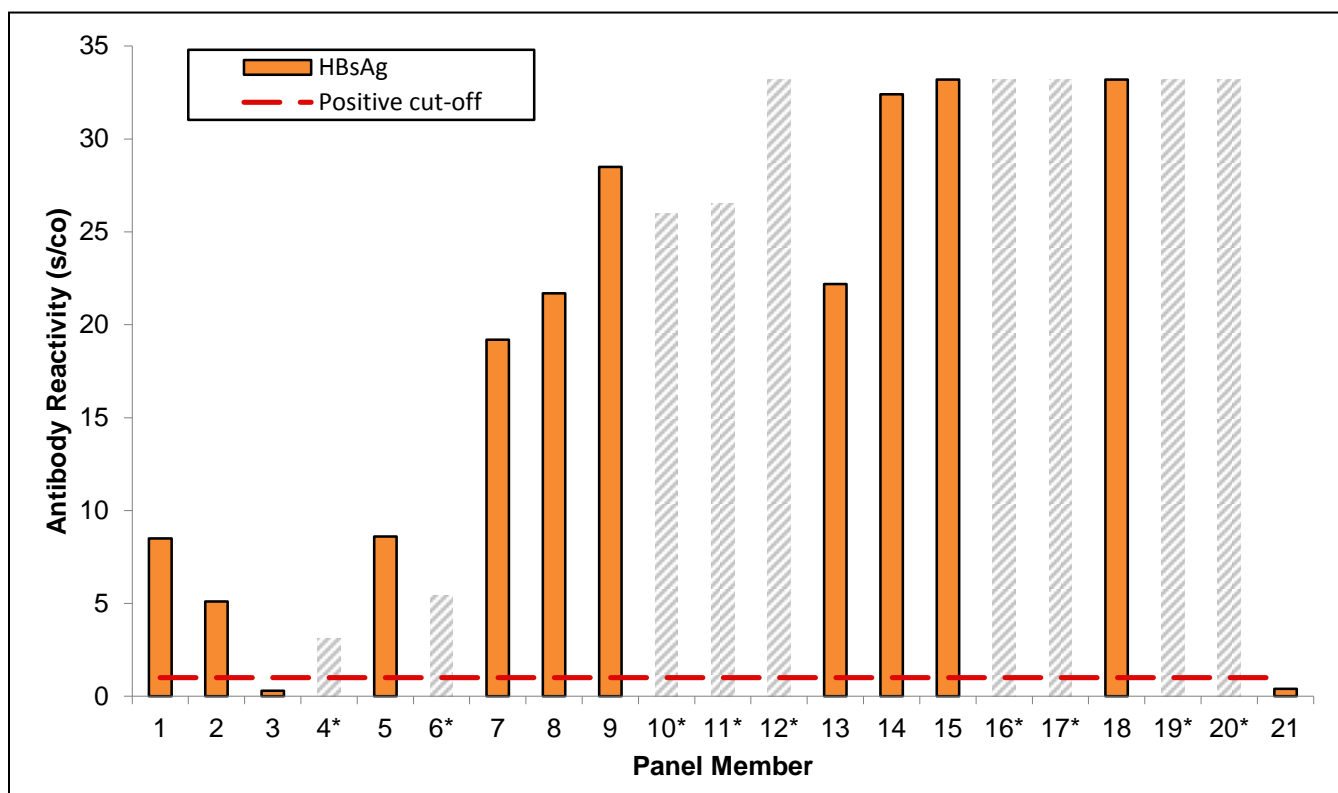
AccuSet™ HBsAg Mixed Titer Performance Panel Modified is a 12 member, 1.5mL per vial panel of undiluted, naturally-occurring plasma samples. No preservatives were added. This modified panel originates from HBsAg Mixed Titer Performance Panel 0805-0217 (PHA207-1.5). Panel members 4, 6, 10, 11, 12, 16, 17, 19 and 20 from the original 21-member panel are no longer available.

This data sheet includes test results from twelve commercially available HBsAg assays including one quantitative method and one rapid test, an HBsAg neutralization method, and tests for several other HBV markers. Low HBsAg members challenge test kit sensitivity. High members can challenge neutralization assays or detect hook effects.

CAUTION: Potentially infectious materials. Follow Universal Precautions. All panel members were found negative for anti-HIV and anti-HCV.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated exactly.

AccuSet™ HBsAg Mixed Titer Performance Panel Modified



*This graph demonstrates HBsAg levels among panel members with the Genetic Systems EIA.
Members no longer available. Data are provided for informational purposes only.

AccuSet™ HBsAg Mixed Titer
 Performance Panel Modified
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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #
0805-0217-01	9124972	NA
0805-0217-02	10000793	NA
0805-0217-03	10000795	NA
0805-0217-04*	9229673	NA
0805-0217-05	9121555	BD110521
0805-0217-06*	9117817	BD110479
0805-0217-07	9121527	BD110532
0805-0217-08	10000703	BD226041
0805-0217-09	9120194	BD110068
0805-0217-10*	9229675	BD106646
0805-0217-11*	9233742	BD107170
0805-0217-12*	9233743	BD107170
0805-0217-13	9109960	BD110459
0805-0217-14	9117923	NA
0805-0217-15	9120438	BD110512
0805-0217-16*	9145770	NA
0805-0217-17*	10000737	NA
0805-0217-18	10000738	NA
0805-0217-19*	9122710	BD110517
0805-0217-20*	9145709	NA
0805-0217-21	9252280	NA

NA = Not Available

*Members no longer available. Data are provided for informational purposes only.

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HBsAg¹

Panel Member	Abbott ARCHITECT HBsAg (s/co)	Abbott ARCHITECT HBsAg (IU/mL)	Abbott PRISM HBsAg (s/co)	Dade Behring Enzygnost HBsAg (s/co)	DiaSorin Liaison HBsAg (Index)
0805-0217-01	4.2	0.34	10.5	8.6	6.1
0805-0217-02	2.9	0.21	6.6	5.3	2.9
0805-0217-03	0.5	0.01	0.3	0.2	0.3
0805-0217-04*	1.9	0.08	1.9	3.5	2.9
0805-0217-05	3.8	0.33	7.8	8.0	5.6
0805-0217-06*	6.3	0.21	7.2	5.1	6.1
0805-0217-07	15.0	1.08	30.0	14.1	9.7
0805-0217-08	21.6	0.97	24.2	36.7	32.5
0805-0217-09	33.2	1.29	35.7	45.5	54.0
0805-0217-10*	18.2	1.22	34.7	26.7	19.0
0805-0217-11*	16.6	1.17	28.2	16.1	17.0
0805-0217-12*	21.5	1.91	47.3	45.1	33.0
0805-0217-13	15.5	1.27	34.1	34.8	33.5
0805-0217-14	33.5	2.23	62.8	45.0	64.0
0805-0217-15	4784.0	4187.00²	545.0	>49.2	>240
0805-0217-16*	4788.0	3095.00²	591.0	>49.2	>240
0805-0217-17*	127.2	6.87	139.0	>49.2	189.5
0805-0217-18	5439.3	15282.00²	695.6	>49.2	>240
0805-0217-19*	3259.0	697.00²	433.0	>49.2	>240
0805-0217-20*	5414.8	11277.00²	862.7	>49.2	>240
0805-0217-21	0.6	0.02	0.8	0.7	0.3
Test Date	21-Sep-11	23-Jan-12	19-Jan-12	16-Mar-12; 08-Jun-12	01-Dec-11/ 01-Feb-12
Test Site	SC	RL	RL	SC	RL
Kit Part Code	1L80	6C36-32	6D19-68	OPFM03	310100
Kit Lot No.	05398LF00	7214LF00	05186M600	40674/40761	040057
Kit Exp. Date	02-Feb-12	09-May-12	08-Apr-12	01-Sep-12; 12-Oct-12	26-Jun-12
Kit Regulatory Status	IVD	CE	CE	CE/IVD	CE

¹Results are means of duplicates. For results expressed as signal to cutoff ratios (s/co) or Index, ratios ≥ 1.0 are considered reactive and are noted in bold red. For results expressed as IU/mL, values ≥ 0.05 are considered reactive and are noted in bold red.

²Results were generated on samples that were diluted 1:100.

*Members no longer available. Data are provided for informational purposes only.

SC = SeraCare; RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformance Europeene or CE Marking

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HBsAg¹

Panel Member	DiaSorin ETI- MAK-2 Plus HBsAg (s/co)	DSI-EIA- HBsAg-0.01 (s/co)	Genetic Systems EIA 3.0 HBsAg (s/co)	Ortho Vitros ECi HBsAg (s/co)	Roche Elecsys HBsAg (s/co)	Siemens ADVIA Centaur HBsAg (s/co)
0805-0217-01	2.8	30.8	8.5	4.4	7.9	5.5
0805-0217-02	1.8	16.8	5.1	2.7	5.3	3.8
0805-0217-03	0.3	0.6	0.3	0.1	0.6	0.1
0805-0217-04*	1.2	13.5	3.1	1.1	2.9	2.1
0805-0217-05	2.9	27.1	8.6	5.0	6.9	6.3
0805-0217-06*	4.5	38.3	5.4	8.2	14.6	13.7
0805-0217-07	9.3	30.2	19.2	8.0	8.7	4.1
0805-0217-08	10.2	>39.0	21.7	21.8	35.8	37.0
0805-0217-09	20.6	>39.0	28.5	36.1	17.1	32.1
0805-0217-10*	12.8	>39.0	26.0	15.8	51.3	6.6
0805-0217-11*	12.6	>39.0	26.5	15.8	22.8	15.6
0805-0217-12*	17.0	>39.0	>33.2	42.7	60.8	64.3
0805-0217-13	13.2	>39.0	22.2	32.5	41.4	19.5
0805-0217-14	14.6	>39.0	32.4	42.2	53.7	47.3
0805-0217-15	58.8	>39.0	>33.2	7410.0	7819.0	>1000
0805-0217-16*	58.8	>39.0	>33.2	8980.0	9679.0	>1000
0805-0217-17*	57.0	>39.0	>33.2	176.5	240.1	278.0
0805-0217-18	58.8	>39.0	>33.2	3750.0	4641.0	>1000
0805-0217-19*	58.8	>39.0	>33.2	6550.0	7829.0	>1000
0805-0217-20*	58.8	>39.0	>33.2	3880.0	4219.0	>1000
0805-0217-21	0.3	0.7	0.4	0.0	0.7	0.3
Test Date	13-Oct-11	06-Feb-12	03-Oct-11/ 06-Dec-11	17-Nov-11	02-Dec-11	21-Nov-11
Test Site	SC	SC	SC	RL	RL	RL
Kit Part Code	P001932	B-1254	32591	SP6801322	04697787-190	03393362
Kit Lot No.	0710290A/1	44	172FCC-05	7150	164 271-01/ 165 577-01	79027159
Kit Exp. Date	26-Oct-11	11-Nov-13	26-Apr-12	24-Aug-12	30-Apr-12/ 31-Jul-12	31-Jul-12
Kit Regulatory Status	IVD	IVD	IVD	IVD	IVD	IVD

¹Results are means of at least duplicates except for Roche Elecsys which was run in singlicate. For results expressed as signal to cutoff ratios (s/co), ratios ≥ 1.0 are considered reactive and are noted in bold red.

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HBsAg Confirmatory, HBsAg Rapid and HBV DNA

Panel Member	Abbott ARCHITECT Neutralization HBsAg (%)	Inverness Medical Determine HBsAg (Rapid)	Roche TaqMan HBV DNA (c/mL)
0805-0217-01	91.4	NEG	2.6 x 10 ⁴
0805-0217-02	92.1	NEG	4.7 x 10 ³
0805-0217-03	NA	NEG	BLD
0805-0217-04*	98.4	NEG	4.2 x 10 ³
0805-0217-05	97.5	NEG	3.0 x 10 ⁴
0805-0217-06*	96.1	NEG	1.5 x 10 ⁵
0805-0217-07	98.5	NEG	1.1 x 10 ⁵
0805-0217-08	98.8	NEG	3.6 x 10 ⁴
0805-0217-09	98.2	NEG	1.3 x 10 ⁵
0805-0217-10*	99.1	NEG	6.4 x 10 ⁴
0805-0217-11*	96.5	NEG	1.2 x 10 ⁵
0805-0217-12*	98.6	NEG	2.3 x 10 ⁵
0805-0217-13	97.5	NEG	1.1 x 10 ⁵
0805-0217-14	98.9	POS	BLD
0805-0217-15	92.5 ¹	POS	2.1 x 10 ²
0805-0217-16*	95.9	POS	1.4 x 10 ³
0805-0217-17*	98.7	POS	4.9 x 10 ⁵
0805-0217-18	89.4 ¹	POS	5.3 x 10 ⁴
0805-0217-19*	96.7	POS	3.0 x 10 ⁴
0805-0217-20*	81.1 ¹	POS	5.0 x 10 ²
0805-0217-21	NA	NEG	BLD
Test Date	12-Dec-11/ 1-Jan-12/ 05-Jan-12/11-Jan-12	15-Nov-11	05-Dec-11/06-Dec-11
Test Site	SC	SC	SC
Kit Part Code	1L81	7D2543	03577163190
Kit Lot No.	08575LF00/10410LF00	14317K100	P03738/P08770
Kit Exp. Date	22-Apr-12/11-Jun-12	15-Sep-12	31-Jul-12/30-Jun-13
Kit Regulatory Status	IVD	IVD	IVD

¹Results were generated on samples that were diluted 1:10.

*Members no longer available. Data are provided for informational purposes only.

NA = Not Applicable; NEG = Negative; POS = Positive; BLD = Below Limit of Detection
SC = SeraCare; IVD = In Vitro Diagnostic

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Other HBV Results¹

Panel Member	Abbott ARCHITECT Core Total (s/co)	Abbott ARCHITECT Core-IgM (s/co)	DiaSorin ETI-EBK Plus HBeAg (s/co)
0805-0217-01	0.1	0.1	0.1
0805-0217-02	0.2	0.0	0.1
0805-0217-03	0.2	0.1	0.0
0805-0217-04*	0.1	0.1	0.1
0805-0217-05	0.1	0.1	0.3
0805-0217-06*	0.2	0.1	1.8
0805-0217-07	0.1	0.0	0.4
0805-0217-08	0.1	0.0	0.2
0805-0217-09	0.1	0.0	1.2
0805-0217-10*	0.1	0.0	0.5
0805-0217-11*	0.1	0.1	0.6
0805-0217-12*	0.2	0.0	1.4
0805-0217-13	0.1	0.1	1.6
0805-0217-14	11.1	0.1	0.0
0805-0217-15	11.1	0.1	0.1
0805-0217-16*	11.6	0.3	0.0
0805-0217-17*	0.3	0.1	4.7
0805-0217-18	12.6	0.1	0.1
0805-0217-19*	11.0	0.1	0.1
0805-0217-20*	11.3	0.4	0.1
0805-0217-21	0.1	0.0	0.0
Test Date	17-Nov-11/21-Nov-11	17-Nov-11/21-Nov-11	17-Nov-11
Test Site	SC	SC	SC
Kit Part Code	6L22	6L23	P001930
Kit Lot No.	02124Q100/06349LI00	02026LI00/96321Q100	0600380A
Kit Exp. Date	24-Feb-12/30-Jun-12	02-Aug-12/01-May-12	19-May-12
Kit Regulatory Status	IVD	IVD	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