

# HBsAg Mixed Titer AccuSet™ Performance Panel Modified PHA207(M) (0805-0217)

## DATA SHEET

### OVERVIEW

HBsAg Mixed Titer AccuSet™ Performance Panel Modified is a 20 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 PHA207-1.5. Panel member #12 from the original 21-member panel is no longer available.

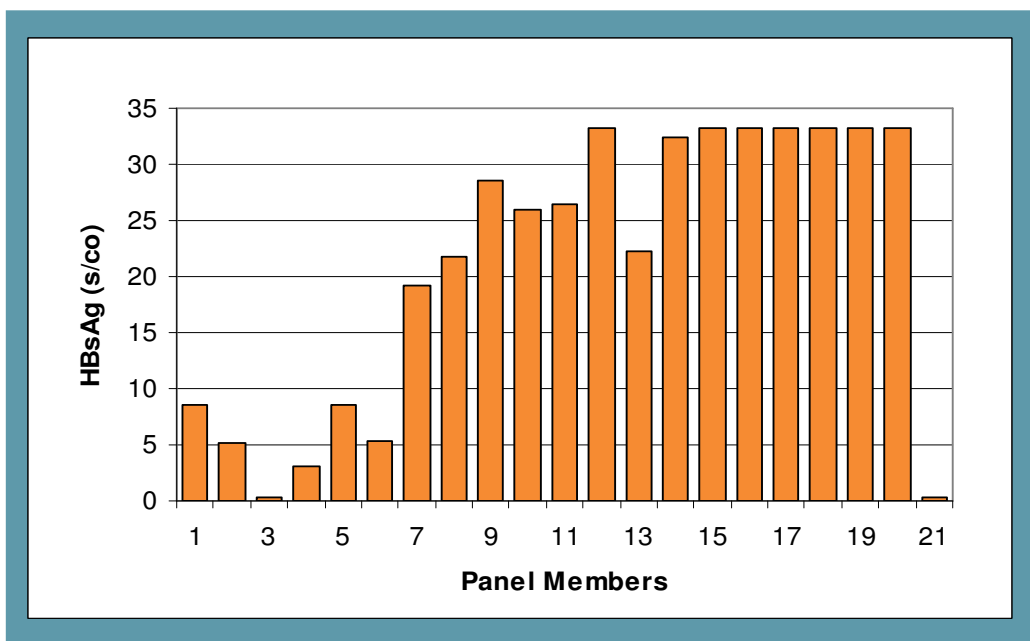
This data sheet includes test results from twelve commercially available HBsAg assays including one quantitative method and one rapid test, an HBsAg neutralization method, and tests for several other HBV markers. Low HBsAg members challenge test kit sensitivity. High members can challenge neutralization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

**For assistance, contact SeraCare Technical Support at 508.244.6400**

**HBsAg Mixed Titer Performance Panel**



*This graph demonstrates HBsAg levels among panel members with the Genetic Systems EIA. Panel member #12 is no longer available. Data are provided for informational purposes only.*

# HBsAg Mixed Titer AccuSet™ Performance Panel Modified PHA207(M) (0805-0217)

## DATA SHEET

### HBsAg<sup>1</sup>

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)
PHA207-01	4.2	0.34	10.5	8.6	6.1
PHA207-02	2.9	0.21	6.6	5.3	2.9
PHA207-03	0.5	0.01	0.3	0.2	0.3
PHA207-04	1.9	0.08	1.9	3.5	2.9
PHA207-05	3.8	0.33	7.8	8.0	5.6
PHA207-06	6.3	0.21	7.2	5.1	6.1
PHA207-07	15.0	1.08	30.0	14.1	9.7
PHA207-08	21.6	0.97	24.2	36.7	32.5
PHA207-09	33.2	1.29	35.7	45.5	54.0
PHA207-10	18.2	1.22	34.7	26.7	19.0
PHA207-11	16.6	1.17	28.2	16.1	17.0
PHA207-12 <sup>2</sup>	21.5	1.91	47.3	45.1	33.0
PHA207-13	15.5	1.27	34.1	34.8	33.5
PHA207-14	33.5	2.23	62.8	45.0	64.0
PHA207-15	4784.0	4187.00*	545.0	>49.2	>240
PHA207-16	4788.0	3095.00*	591.0	>49.2	>240
PHA207-17	127.2	6.87	139.0	>49.2	189.5
PHA207-18	5439.3	15282.00*	695.6	>49.2	>240
PHA207-19	3259.0	697.00*	433.0	>49.2	>240
PHA207-20	5414.8	11277.00*	862.7	>49.2	>240
PHA207-21	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

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

<sup>2</sup>Panel member #12 is no longer available. Data are provided for informational purposes only.

\*Results were generated on samples that were diluted 1:100

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

# HBsAg Mixed Titer AccuSet™ Performance Panel Modified PHA207(M) (0805-0217)

## DATA SHEET

### HBsAg<sup>1</sup>

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 Elecys HBsAg (s/co)	Siemens ADVIA Centaur HBsAg (s/co)
PHA207-01	2.8	30.8	8.5	4.4	7.9	5.5
PHA207-02	1.8	16.8	5.1	2.7	5.3	3.8
PHA207-03	0.3	0.6	0.3	0.1	0.6	0.1
PHA207-04	1.2	13.5	3.1	1.1	2.9	2.1
PHA207-05	2.9	27.1	8.6	5.0	6.9	6.3
PHA207-06	4.5	38.3	5.4	8.2	14.6	13.7
PHA207-07	9.3	30.2	19.2	8.0	8.7	4.1
PHA207-08	10.2	>39.0	21.7	21.8	35.8	37.0
PHA207-09	20.6	>39.0	28.5	36.1	17.1	32.1
PHA207-10	12.8	>39.0	26.0	15.8	51.3	6.6
PHA207-11	12.6	>39.0	26.5	15.8	22.8	15.6
PHA207-12 <sup>2</sup>	17.0	>39.0	>33.2	42.7	60.8	64.3
PHA207-13	13.2	>39.0	22.2	32.5	41.4	19.5
PHA207-14	14.6	>39.0	32.4	42.2	53.7	47.3
PHA207-15	58.8	>39.0	>33.2	7410.0	7819.0	>1000
PHA207-16	58.8	>39.0	>33.2	8980.0	9679.0	>1000
PHA207-17	57.0	>39.0	>33.2	176.5	240.1	278.0
PHA207-18	58.8	>39.0	>33.2	3750.0	4641.0	>1000
PHA207-19	58.8	>39.0	>33.2	6550.0	7829.0	>1000
PHA207-20	58.8	>39.0	>33.2	3880.0	4219.0	>1000
PHA207-21	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

<sup>1</sup>Results are means of at least duplicates except for Roche Elecys which was run in singlicate. For results expressed as signal to cutoff ratios (s/co), ratios  $\geq 1.0$  are considered reactive and are noted in red.

<sup>2</sup>Panel member #12 is no longer available. Data are provided for informational purposes only.

SC = SeraCare; RL = Reference Lab; IVD = In Vitro Diagnostic

# HBsAg Mixed Titer AccuSet™ Performance Panel Modified PHA207(M) (0805-0217)

## DATA SHEET

### HBsAg Confirmatory, HBsAg Rapid and HBV DNA

Panel Member	Abbott ARCHITECT Neutralization HBsAg (%)	Inverness Medical Determine HBsAg (Rapid)	Roche TaqMan HBV DNA (c/mL)
PHA207-01	91.4	NEG	2.6 x 10 <sup>4</sup>
PHA207-02	92.1	NEG	4.7 x 10 <sup>3</sup>
PHA207-03	NA	NEG	BLD
PHA207-04	98.4	NEG	4.2 x 10 <sup>3</sup>
PHA207-05	97.5	NEG	3.0 x 10 <sup>4</sup>
PHA207-06	96.1	NEG	1.5 x 10 <sup>5</sup>
PHA207-07	98.5	NEG	1.1 x 10 <sup>5</sup>
PHA207-08	98.8	NEG	3.6 x 10 <sup>4</sup>
PHA207-09	98.2	NEG	1.3 x 10 <sup>5</sup>
PHA207-10	99.1	NEG	6.4 x 10 <sup>4</sup>
PHA207-11	96.5	NEG	1.2 x 10 <sup>5</sup>
PHA207-12 <sup>1</sup>	98.6	NEG	2.3 x 10 <sup>5</sup>
PHA207-13	97.5	NEG	1.1 x 10 <sup>5</sup>
PHA207-14	98.9	POS	BLD
PHA207-15	92.5**	POS	2.1 x 10 <sup>2</sup>
PHA207-16	95.9	POS	1.4 x 10 <sup>3</sup>
PHA207-17	98.7	POS	4.9 x 10 <sup>5</sup>
PHA207-18	89.4**	POS	5.3 x 10 <sup>4</sup>
PHA207-19	96.7	POS	3.0 x 10 <sup>4</sup>
PHA207-20	81.1**	POS	5.0 x 10 <sup>2</sup>
PHA207-21	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

<sup>1</sup>Panel member #12 is no longer available. Data are provided for informational purposes only.

\*\*Results were generated on samples that were diluted 1:10

NA = Not Applicable; NEG = Negative; POS = Positive; BLD = Below Limit of Detection

SC = SeraCare; IVD = In Vitro Diagnostic

# HBsAg Mixed Titer AccuSet™ Performance Panel Modified PHA207(M) (0805-0217)

## DATA SHEET

### Other HBV Results<sup>1</sup>

Panel Member	Abbott ARCHITECT Core Total (s/co)	Abbott ARCHITECT Core-IgM (s/co)	DiaSorin ETI-EBK Plus HBeAg (s/co)
PHA207-01	0.1	0.1	0.1
PHA207-02	0.2	0.0	0.1
PHA207-03	0.2	0.1	0.0
PHA207-04	0.1	0.1	0.1
PHA207-05	0.1	0.1	0.3
PHA207-06	0.2	0.1	1.8
PHA207-07	0.1	0.0	0.4
PHA207-08	0.1	0.0	0.2
PHA207-09	0.1	0.0	1.2
PHA207-10	0.1	0.0	0.5
PHA207-11	0.1	0.1	0.6
PHA207-12 <sup>2</sup>	0.2	0.0	1.4
PHA207-13	0.1	0.1	1.6
PHA207-14	11.1	0.1	0.0
PHA207-15	11.1	0.1	0.1
PHA207-16	11.6	0.3	0.0
PHA207-17	0.3	0.1	4.7
PHA207-18	12.6	0.1	0.1
PHA207-19	11.0	0.1	0.1
PHA207-20	11.3	0.4	0.1
PHA207-21	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

<sup>1</sup>Results are means of at least duplicates. For results expressed as signal to cutoff ratios (s/co), ratios  $\geq 1.0$  are considered reactive and are noted in red.

<sup>2</sup>Panel member #12 is no longer available. Data are provided for informational purposes only.

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The Package Insert for this panel in PDF form can be found at [www.seracare.com](http://www.seracare.com)

A printed copy of the Package Insert or Data Sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

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