HBsAg Low Titer AccuSet™ Performance Panel Modified

DATA SHEET

PHA107(M) (0805-0304)

OVERVIEW

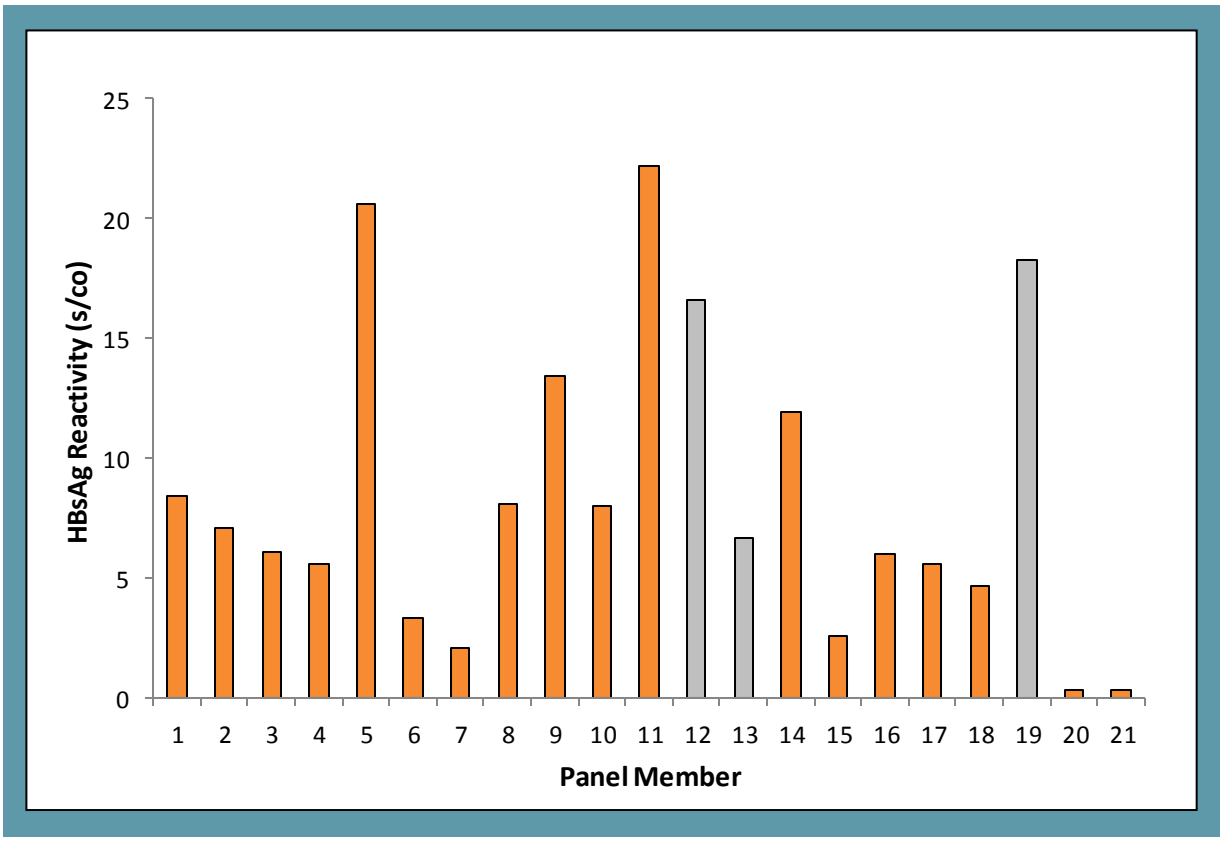
HBsAg Low Titer AccuSet™ Performance Panel (0805-0304) is a modified 18-member panel originating from HBsAg Low Titer Performance Panel PHA107-1.5. Panel members 12, 13, and 19 are no longer available. Panel members are naturally-occurring plasma samples from different individuals with test results from eleven commercially available HBsAg assays, including one quantitative method and one rapid test, an HBsAg neutralization method, and tests for several other HBV markers.

All members were processed by filtration through a 0.8 µm filters. No preservatives were added.

CAUTION: Potentially infectious materials. Follow Universal Precautions. All panel members were found negative for anti-HIV and anti-HCV. This does not ensure the absence of these or other pathogens.

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.

HBsAg Low Titer AccuSet™ Performance Panel



This graph demonstrates the breadth of HBsAg reactivity amongst panel members utilizing the Genetic Systems EIA test method. Panel members 12, 13, and 19 are no longer available; data are provided for informational purposes only.

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HBsAg[1]

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)
PHA107-01	4.4	0.18	5.9	7.0	5.3
PHA107-02	7.1	0.41	14.4	12.7	14.0
PHA107-03	2.8	0.19	6.7	5.7	7.1
PHA107-04	4.2	0.15	4.5	7.4	19.0
PHA107-05	12.9	0.87	30.3	20.9	18.5
PHA107-06	2.4	0.15	5.6	4.6	3.3
PHA107-07	1.7	0.03	1.2	2.1	1.8
PHA107-08	4.5	0.32	10.2	8.3	6.4
PHA107-09	13.8	0.82	33.8	12.0	19.5
PHA107-10	3.3	0.16	8.2	6.3	2.5
PHA107-11	17.7	1.04	30.0	27.8	22.0
PHA107-12*	6.9	0.49	14.0	11.5	8.4
PHA107-13*	4.3	0.25	9.3	6.8	4.0
PHA107-14	6.8	0.53	19.0	11.6	8.8
PHA107-15	2.1	0.04	1.8	2.9	1.7
PHA107-16	7.9	0.28	9.9	3.5	6.1
PHA107-17	7.6	0.11	3.8	6.5	8.0
PHA107-18	7.0	0.15	4.4	7.3	6.4
PHA107-19*	20.0	1.19	46.8	32.5	8.6
PHA107-20	0.5	0.00	0.2	0.2	0.2
PHA107-21	0.6	0.00	0.2	0.1	0.2
Test Date	21-Sep-11	01-Mar-12	19-Jan-12	16-Mar-12	01-Dec-11
Test Site	SC	RL	RL	SC	RL
Kit Part Code	1L80	6C36	6D19-68	OPFM03	310100
Kit Lot No.	05398LF00	12515LFOO	05186M600	40674	040057
Kit Exp. Date	02-Feb-12	19-Aug-12	08-Apr-12	01-Sep-12	26-Jun-12
Kit Regulatory Status	IVD	CE	CE	CE/IVD	CE

[1]Results are mean results of duplicate testing. For results expressed as signal to cutoff ratios (s/co) and Index, ratios ≥1.0 are considered reactive and are noted in red. For results expressed as IU/mL, values ≥0.05 are considered reactive and are noted in red.
RL = Reference Lab; SC = SeraCare
CE = Conformité Européenne or CE Marking; IVD = In Vitro Diagnostic Use
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HBsAg[1]

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)
PHA107-01	3.1	36.0	8.4	4.8	9.6	3.6
PHA107-02	5.0	>39.0	7.1	8.3	9.5	10.0
PHA107-03	1.6	20.4	6.1	4.0	5.0	2.2
PHA107-04	2.8	25.7	5.6	3.6	6.1	7.1
PHA107-05	8.9	>39.0	20.6	17.7	21.7	16.4
PHA107-06	1.6	15.9	3.3	2.1	3.5	3.3
PHA107-07	1.0	11.6	2.1	1.5	2.3	3.0
PHA107-08	2.9	11.8	8.1	5.9	7.4	7.4
PHA107-09	11.1	>39.0	13.4	25.1	27.9	34.4
PHA107-10	2.8	28.6	8.0	3.0	3.0	2.4
PHA107-11	9.0	>39.0	22.2	14.2	23.1	25.5
PHA107-12*	5.1	38.5	16.6	2.4	8.4	3.5
PHA107-13*	2.6	27.3	6.7	1.6	5.9	9.6
PHA107-14	3.2	>39.0	11.9	5.8	14.2	6.8
PHA107-15	1.2	8.6	2.6	0.8	2.6	2.5
PHA107-16	3.8	>39.0	6.0	2.2	14.4	15.9
PHA107-17	4.2	30.1	5.6	3.3	10.1	17.8
PHA107-18	6.7	30.9	4.7	5.4	10.4	17.1
PHA107-19*	8.8	>39.0	18.3	25.8	29.1	40.6
PHA107-20	0.2	0.4	0.3	0.1	0.5	0.1
PHA107-21	0.3	1.0	0.3	0.1	0.4	0.1
Test Date	13-Oct-11	06-Feb-12	03-Oct-11 02-Dec-11	17-Nov-11 14-Jan-12	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	7150/7170	164 271-01 165 577-01	79027159
Kit Exp. Date	26-Oct-11	11-Nov-13	26-Apr-12	24-Aug-12 10-Oct-12	30-Apr-12 31-Jul-12	31-Jul-12
Kit Regulatory Status	IVD	IVD/CE	IVD	IVD	IVD	IVD

[1]Results are mean results of duplicate testing; Roche Elecsys was run in singlicate. For results expressed as signal to cutoff ratios (s/co), ratios ≥1.0 are considered reactive and are noted in red.
RL = Reference Lab; SC = SeraCare; IVD = In Vitro Diagnostic Use
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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 (copies/mL)
PHA107-01	100.0	NEG	2.7×10^4
PHA107-02	97.8	NEG	1.4×10^4
PHA107-03	97.5	NEG	1.3×10^3
PHA107-04	97.9	NEG	9.8×10^3
PHA107-05	98.7	NEG	1.0×10^5
PHA107-06	98.1	NEG	1.3×10^4
PHA107-07	95.1	NEG	5.2×10^4
PHA107-08	97.0	NEG	1.1×10^4
PHA107-09	97.2	NEG	2.2×10^5
PHA107-10	96.5	NEG	4.1×10^4
PHA107-11	99.2	NEG	7.4×10^4
PHA107-12*	98.8	NEG	3.9×10^4
PHA107-13*	97.7	NEG	5.1×10^4
PHA107-14	98.1	NEG	3.3×10^4
PHA107-15	98.4	NEG	9.9×10^3
PHA107-16	97.6	NEG	2.7×10^2
PHA107-17	99.1	NEG	BLD
PHA107-18	97.9	NEG	BLD
PHA107-19*	92.3	NEG	3.7×10^2
PHA107-20	NA	NEG	BLD
PHA107-21	NA	NEG	BLD
Test Date	12-Dec-11/05-Jan-12/11-Jan-12	15-Nov-11	05-Dec-11/ 06-Dec-11/ 13-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

NA = not available
SC = SeraCare
IVD = in vitro diagnostic use
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Other HBV Results[1]

Panel Member	Abbott ARCHITECT Core Total (s/co)	Abbott ARCHITECT Core IgM (s/co)	Diasorin ETI-EBK Plus HBeAg (s/co)
PHA107-01	0.3	0.1	1.1
PHA107-02	0.1	0.0	0.2
PHA107-03	0.2	0.1	0.1
PHA107-04	0.2	0.0	0.1
PHA107-05	0.1	0.1	0.6
PHA107-06	0.2	0.0	0.2
PHA107-07	0.1	0.0	0.4
PHA107-08	0.1	0.0	0.2
PHA107-09	0.2	0.1	**2.4**
PHA107-10	0.1	0.0	0.3
PHA107-11	0.1	0.0	0.7
PHA107-12*	0.1	0.1	0.3
PHA107-13*	0.2	0.1	0.3
PHA107-14	0.1	0.0	0.3
PHA107-15	**9.5**	0.1	0.3
PHA107-16	**9.3**	**1.7**	0.1
PHA107-17	**10.0**	**32.0**	0.3
PHA107-18	**9.8**	**32.1**	0.4
PHA107-19*	**9.1**	**19.1**	0.1
PHA107-20	0.1	0.1	0.1
PHA107-21	0.2	0.1	0.1
Test Date	21-Nov-11	21-Nov-11	17-Nov-11
Test Site	SC	SC	SC
Kit Part Code	6L22	6L23	P001930
Kit Lot No.	06349LI00	96321Q100	0600380A
Kit Exp. Date	30-Jun-12	01-May-12	19-May-12
Kit Regulatory Status	IVD	IVD	IVD

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The Package Insert for this panel in PDF form can be found at www.seracare.com

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