

OVERVIEW

This Data Sheet contains test results specific for HBV Seroconversion Panel PHM936, genotype A. PHM936 is an 8 member HBV seroconversion with close bleeds collected over 26 days. Member 1 challenges the sensitivity of the eight HBsAg methods and the four HBV DNA methods tested, and Member 4 is a good low-titer HBeAg sample.

Panel Members are undiluted aliquots from plasma units collected from a single donor. No preservatives were added.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were found positive for HBsAg; all were found negative for anti-HIV and anti-HCV. All panel members were found negative for anti-HBs and anti-HBe.

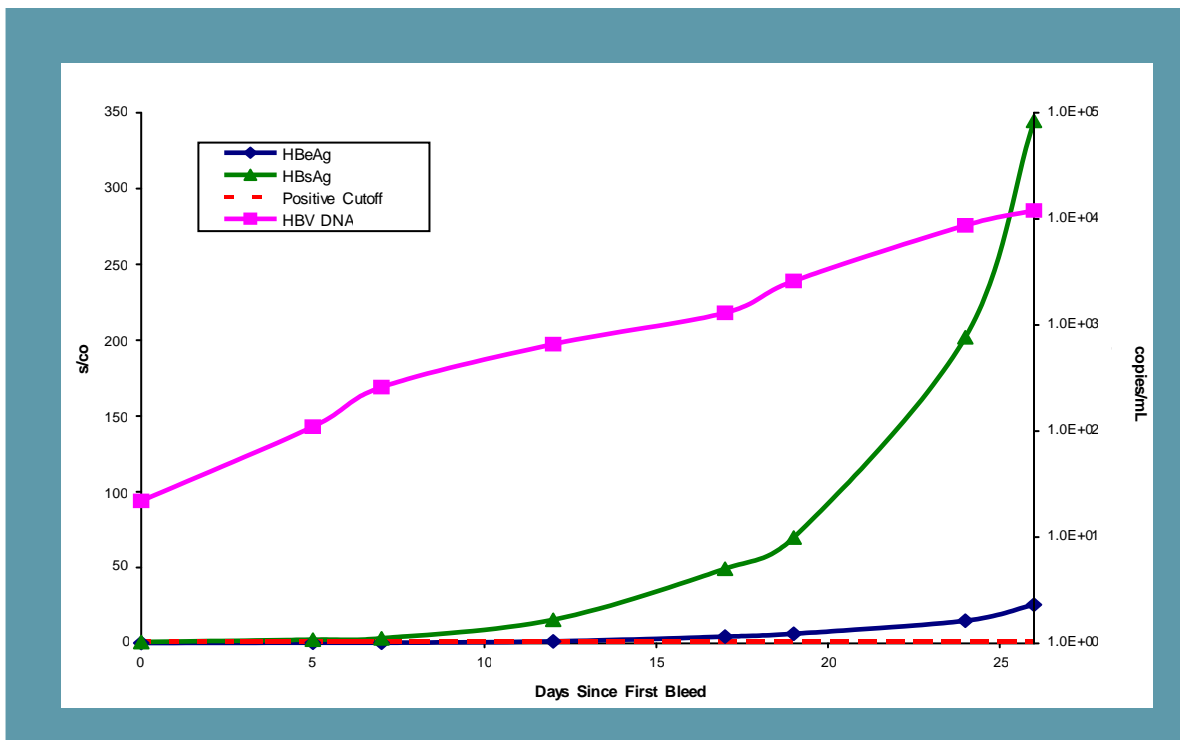
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Not for use in diagnostic procedures.

Data are offered 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

EVOLUTION OF HBV MARKERS IN EARLY INFECTION



A printed Package Insert (PI) and Data Sheet may be requested by email to info@seracare.com, or by phone to 508.244.6400

This graph demonstrates the evolution of early HBV infection, illustrated with test results over time for different analytes.

DATA SHEET

PHM936

HBsAg¹

Panel Member	Bleed Date	Days Since 1 st Bleed	Abbott HBsAg ARCHITECT IU/mL	Abbott HBsAg PRISM s/co	Abbott HBsAg AxSYM s/co	DiaSorin HBsAg ETI-MAK-2-Plus s/co
PHM936-01	19-May-00	0	1.1	4.6	0.9	0.8
PHM936-02	24-May-00	5	2.8	51.9	1.8	1.6
PHM936-03	26-May-00	7	3.9	107.3	1.9	2.3
PHM936-04	31-May-00	12	10.6	156.7	5.4	7.8
PHM936-05	05-Jun-00	17	46.8	4.6	14.9	24.4
PHM936-06	07-Jun-10	19	75.6	12.4	23.1	37.7
PHM936-07	12-Jun-00	24	230.9	93.2	39.8	>61.2
PHM936-08	14-Jun-00	26	329.6	219.2	51.3	>61.2
Test Date			20-Jul-10	20-Jul-10 & 10-Aug-10	19-Jul-10	12-Jul-10
Test Site			RL	RL	SC	SC
Kit Part Code			1L80-10	6D19-68	9B01-20	P001932
Kit Lot No.			88497LF00	85236M500	84914M500	0710250A
Kit Exp Date			18-Nov-10	26-Oct-10	08-Sep-10	30-Oct-10

Panel Member	Bleed Date	Days Since 1 st Bleed	Genetic Systems HBsAg EIA 3.0 s/co	Ortho HBsAg Vitros ECI s/co	Roche HBsAg Elecsys s/co	Siemens HBsAg Advia Centaur s/co
PHM936-01	19-May-00	0	2.1	0.4	1.1	0.9
PHM936-02	24-May-00	5	4.7	1.7	2.6	2.5
PHM936-03	26-May-00	7	6.7	3.8	3.5	3.3
PHM936-04	31-May-00	12	20.4	17.7	12.1	15.6
PHM936-05	05-Jun-00	17	>33.3	54.4	34.3	49.3
PHM936-06	07-Jun-00	19	>33.3	89.8	57.2	69.8
PHM936-07	12-Jun-00	24	>33.3	244.0	187.2	201.9
PHM936-08	14-Jun-00	26	>33.3	383.0	283.9	344.7
Test Date			21-Jul-10	21-Jul-10	26-Jul-10	19-Jul-10
Test Site			SC	RL	RL	RL
Kit Part Code			32591	SP6801322	04687787	03393362
Kit Lot No.			015ECC-05	6860	156666-01	149
Kit Exp Date			28-Sep-10	25-Jan-11	31-Aug-10	4-Mar-11

¹ Immunoassay results are means of duplicates expressed as International Units per milliliter ratios (IU/mL) or signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

POS = positive; BLD = below the limit of detection

RL = Reference Lab; SC = SeraCare

HBV DNA

Panel Member	Bleed Date	Days Since 1 st Bleed	Abbott HBV DNA m2000 IU/mL	Gen-Probe PROCLEIX ULTRIO	Roche HBV DNA CAP/CTM v1.0 IU/mL	Roche Cobas Taqscreen MPX Test
PHM936-01	19-May-00	0	2.2 x 10 ¹	POS	BLD	POS
PHM936-02	24-May-00	5	1.1 x 10 ²	POS	8.2 x 10 ¹	POS
PHM936-03	26-May-00	7	2.6 x 10 ²	POS	2.3 x 10 ²	POS
PHM936-04	31-May-00	12	6.6 x 10 ²	POS	4.3 x 10 ²	POS
PHM936-05	05-Jun-00	17	1.3 x 10 ³	POS	1.8 x 10 ³	POS
PHM936-06	07-Jun-00	19	2.6 x 10 ³	POS	2.9 x 10 ³	POS
PHM936-07	12-Jun-00	24	8.7 x 10 ³	POS	1.1 x 10 ⁴	POS
PHM936-08	14-Jun-00	26	1.3 x 10 ⁴	POS	1.2 x 10 ⁴	POS
Test Date			26-Jul-10	10-Sep-10	05-Aug-10	20-Sep-10
Test Site			RL	RL	SC	RL
Kit Part Code			2G34-90	04584252 190	03577163 190	04584252 190
Kit Lot No.			425603	N02761	N 00809	N 02747
Kit Exp Date			16-Aug-11	01-Feb-11	31-Aug-11	28-Feb-11

Other HBV tests¹

Panel Member	Bleed Date	Days Since 1 st Bleed	DiaSorin HBeAg ETI-EBK Plus s/co	Abbott Core-total ARCHITECT co/s	Abbott Core-IgM ARCHITECT s/co
PHM936-01	19-May-00	0	0.2	0.1	0.0
PHM936-02	24-May-00	5	0.4	0.1	0.0
PHM936-03	26-May-00	7	0.4	0.1	0.0
PHM936-04	31-May-00	12	1.3	0.1	0.0
PHM936-05	05-Jun-00	17	4.5	0.1	0.0
PHM936-06	07-Jun-00	19	6.3	0.1	0.0
PHM936-07	12-Jun-00	24	14.9	0.1	0.0
PHM936-08	14-Jun-00	26	25.5	0.1	0.0
Test Date			09-Aug-10	20-Jul-10	05-Aug-10
Test Site			SC	RL	RL
Kit Part Code			P001930	6L22-10	6L23-10
Kit Lot No.			0600340A/1	83622HN00	85066HN00
Kit Exp Date			12-Apr-11	06-Oct-10	02-Sep-11

¹ Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co) or cutoff ratio to signal (co/s). Ratios ≥1.0 are considered reactive and noted in red.

POS = positive; BLD = below the limit of detection
RL = Reference Lab; SC = SeraCare