

**OVERVIEW**

This Data Sheet contains test results specific for HBV Seroconversion Panel PHM939, genotype A. PHM939 is a five member series with close bleeds collected from a single individual over 21 days in 2001. Members 1 through 4 are challenging for many HBsAg assays. HBV DNA is positive from the first collection; other HBV markers are negative as expected in very early infection. Results for six HBsAg methods, including a rapid test, two HBV DNA tests and one test each for other HBV markers are included.

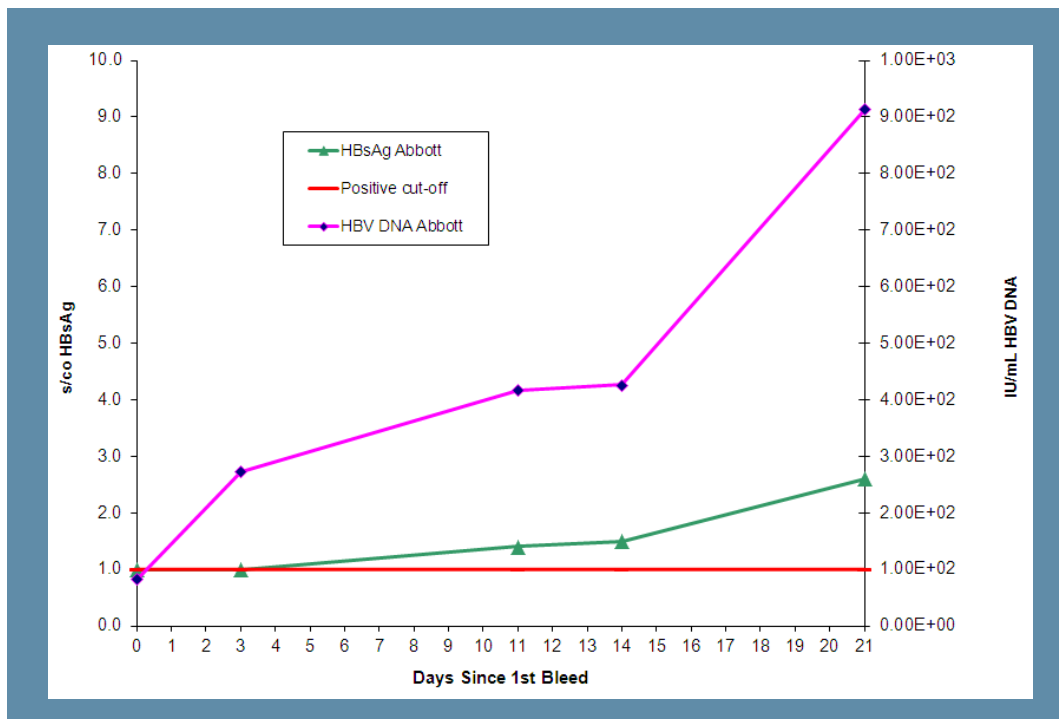
Panel members are undiluted aliquots from plasma units collected from a single donor. No preservatives were added. CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were found positive for HBV DNA; all were found negative for anti-HIV and anti-HCV. This does not ensure the absence of these or other human 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.

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

**EVOLUTION OF HBV MARKERS IN EARLY INFECTION**



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

DATA SHEET

HBsAg<sup>1</sup>

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Abbott ARCHITECT HBsAg Qualitative (s/co)	Alere Determine® HBsAg Result <sup>2</sup>	bioMerieux VIDAS® Hepatitis B Ultra (s/co)	Bio-Rad GS HBsAg EIA 3.0 (s/co)
PHM939-01	16-Jul-01	0	1.0	NEG	pending	0.8
PHM939-02	19-Jul-01	3	1.0	NEG	pending	0.7
PHM939-03	27-Jul-01	11	1.4	NEG	pending	2.0
PHM939-04	30-Jul-01	14	1.5	NEG	pending	1.6
PHM939-05	6-Aug-01	21	2.6	NEG	pending	3.6
Test Date			07-Aug-12	23-Aug-12	pending	27-Jul-12
Test Site			SC	SC	pending	SC
Kit Part Code			1L80	7D2543	pending	32591
Kit Lot No.			16289LF00	14317K100	pending	076GCC-05
Kit Exp. Date			11-Dec-12	15-Sep-12	pending	08-Feb-13
Kit Regulatory Status			FDA IVD	pending	CE	FDA IVD

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	DiaSorin ETI-MAK-2 PLUS HBsAg (s/co)	DiaSorin Liaison® HBsAg (s/co)	Ortho VITROS HBsAg (s/co)	Siemens ADVIA Centaur HBsAg (s/co)
PHM939-01	16-Jul-01	0	0.1	pending	0.1	0.3
PHM939-02	19-Jul-01	3	0.3	pending	0.2	0.4
PHM939-03	27-Jul-01	11	0.7	pending	0.9	1.4
PHM939-04	30-Jul-01	14	0.9	pending	1.0	1.3
PHM939-05	6-Aug-01	21	1.4	pending	2.4	2.3
Test Date			07-Aug-12	pending	15-Aug-12	21-Aug-12
Test Site			SC	pending	RL	RL
Kit Part Code			P001932	pending	6801322	03393362
Kit Lot No.			0710330A	pending	7250	pending
Kit Exp. Date			08-Sep-12	pending	03-Jan-13	pending
Kit Regulatory Status			FDA IVD	CE	FDA IVD	FDA IVD/CE

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

<sup>2</sup> Alere Determine HBsAg is a rapid visually read qualitative Immunoassay. Results are means of duplicates.

POS = positive; NEG = negative; BLD = below the limit of detection; IND = indeterminate; NA = not available, NT = not tested

MFG = Manufacturer; RL = Reference Lab; SC = SeraCare

ASR = analyte specific reagent; CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use; LDT = laboratory developed test;

RUO = research use only

DATA SHEET

HBV DNA

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Abbott RealTime HBV m2000 (IU/mL)	Gen-Probe PROCLEIX ULTRIO Result	Roche HBV DNA CAP/CTM v.2.0 (IU/mL)	Roche cobas® TaqScreen MPX Test Result
PHM939-01	16-Jul-01	0	8.3 x 10 <sup>1</sup>	POS	7.8 x 10 <sup>1</sup>	POS
PHM939-02	19-Jul-01	3	2.7 x 10 <sup>2</sup>	POS	2.1 x 10 <sup>2</sup>	POS
PHM939-03	27-Jul-01	11	4.2 x 10 <sup>2</sup>	POS	5.3 x 10 <sup>2</sup>	POS
PHM939-04	30-Jul-01	14	4.3 x 10 <sup>2</sup>	POS	4.7 x 10 <sup>2</sup>	POS
PHM939-05	6-Aug-01	21	9.1 x 10 <sup>2</sup>	POS	9.2 x 10 <sup>2</sup>	POS
Test Date			15-Aug-12	20-Aug-12	31-Oct-12	11-Oct-12
Test Site			RL	RL	SC	RL
Kit Part Code			2N40-90	302573/302574	05027012 190	045842521 190
Kit Lot No.			435090	607611	R00307	R05128(00000)
Kit Exp. Date			27-Dec-12	15-Mar-14	30-Sep-13	13-Jan-14
Kit Regulatory Status			FDA IVD/CE	FDA IVD/CE	FDA IVD/CE	FDA IVD/CE

Other HBV Tests<sup>1</sup>

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Abbott AxSYM Core™ 2.0 (co/s)	Abbott Core-IgM ARCHITECT (s/co)	DiaSorin ETI-AB-AUK PLUS Anti-HBs (s/co)	DiaSorin ETI-EBK Plus HBeAg (s/co)	DiaSorin ETI-AB-EBK PLUS Anti-HBe (co/s)
PHM939-01	16-Jul-01	0	0.5	0.1	0.4	0.0	0.5
PHM939-02	19-Jul-01	3	0.5	0.0	0.4	0.1	0.5
PHM939-03	27-Jul-01	11	0.5	0.1	0.4	0.1	0.5
PHM939-04	30-Jul-01	14	0.5	0.0	0.2	0.1	0.5
PHM939-05	6-Aug-01	21	0.5	0.0	0.3	0.2	0.5
Test Date			30-Jul-12	30-Jul-12	30-Jul-12	30-Jul-12	30-Jul-12
Test Site			SC	SC	SC	SC	SC
Kit Part Code			8B88-20	6L23	P001931	P001930	P001929
Kit Lot No.			08372M500	02026L100	0650320A	0600400B	0490470B
Kit Exp. Date			27-Jan-13	02-Aug-12	07-Feb-13	26-Feb-13	29-Jan-13
Kit Regulatory Status			FDA IVD	FDA IVD	FDA IVD	FDA IVD	FDA IVD

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

POS = positive; NEG = negative; BLD = below the limit of detection; IND = indeterminate; NA = not available, NT = not tested  
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare  
ASR = analyte specific reagent; CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use; LDT = laboratory developed test;  
RUO = research use only

The Product Insert for this panel in PDF form can be found at [www.seracarecatalog.com](http://www.seracarecatalog.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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March 29, 2013

**SUBJECT: PHM937-939 HBV Seroconversion Panels Storage**

**RECOMMENDED ACTION: Note storage requirements**

Dear Valued SeraCare Customer,

SeraCare Life Sciences is issuing this memo regarding our PHM937, PHM938, and PHM939 HBV Seroconversion Panels. This memo serves to clarify storage requirements for recent lots of these products that contain a -20°C or colder claim on the box and vial labels as well as the Package Inserts.

The listings of products containing this claim are:

PART CODE	LOT NUMBER	DESCRIPTION
PHM937-1.5	123541	HBV Seroconversion Panel
PHM938-1.5	123542	HBV Seroconversion Panel
PHM939-1.5	123540	HBV Seroconversion Panel

Please note that while the labeling remains accurate as stated, storage at -20°C or lower is recommended for serological testing applications, and -70°C is recommended for NAT testing applications.

If you would like more information about this product update, please contact your local SeraCare representative or visit our website at [www.seracarecatalog.com](http://www.seracarecatalog.com)

Thank you for your loyal business with SeraCare Life Sciences.

Sincerely,



Lisa Alexander  
VP Quality and Regulatory  
SeraCare Life Sciences



Christopher Long  
Product Manager  
SeraCare Life Sciences