

**OVERVIEW**

HBV Seroconversion Panel PHM937, genotype A is a five member HBV seroconversion collected from a single individual over 16 days in 2007 with short intervals between bleed dates. Members 2 and 3 are particularly challenging for many HBsAg assays. HBV DNA is positive from the first collection. As expected in very early infection, other HBV markers are negative. Results for five HBsAg methods, three HBV DNA tests and one test each for additional HBV markers are included.

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

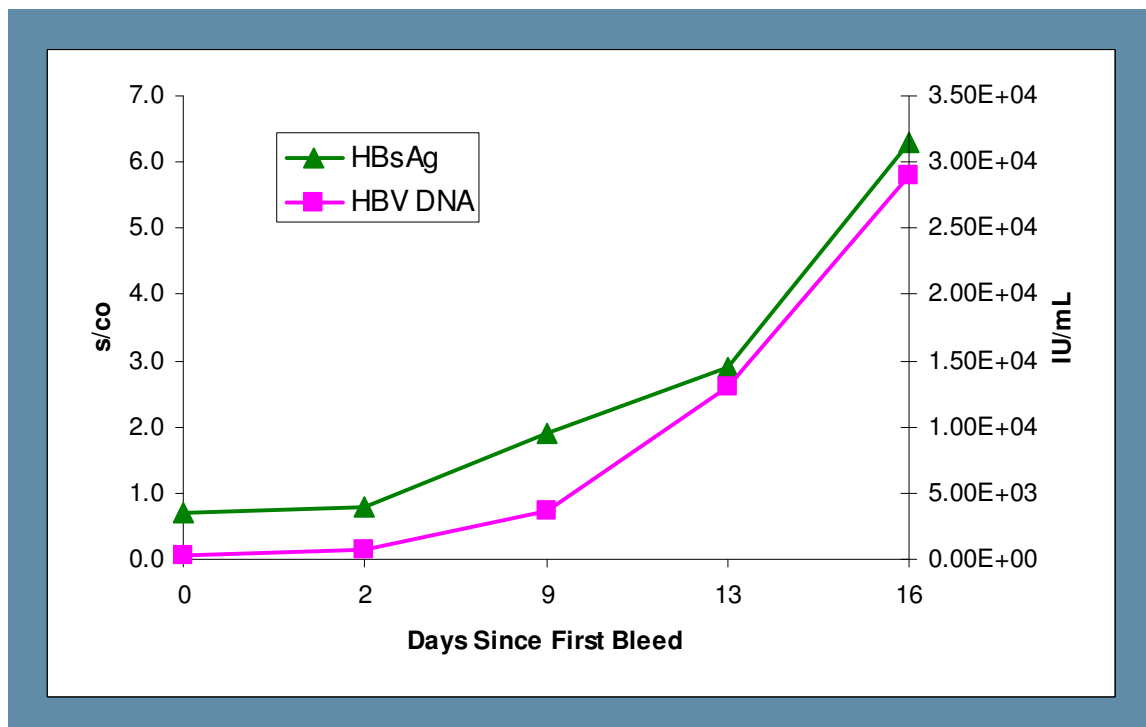
CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were found positive for HBsAg; all were found negative for anti-HIV and anti-HCV. This does not ensure the absence of these or other human pathogens.

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 <sup>®2</sup> HBsAg Result	bioMerieux VIDAS <sup>®</sup> Hepatitis B Ultra (s/co)	Bio-Rad Genetic Systems <sup>™</sup> HBsAg EIA 3.0 (s/co)
PHM937-01	6-Mar-07	0	0.7	Pending	Pending	0.3
PHM937-02	8-Mar-07	2	0.8	Pending	Pending	0.5
PHM937-03	15-Mar-07	9	1.9	Pending	Pending	1.4
PHM937-04	19-Mar-07	13	2.9	Pending	Pending	3.0
PHM937-05	22-Mar-07	16	6.3	Pending	Pending	6.1
Test Date			07-Aug-12		08-Aug-12 & 22-Aug-12	
Test Site			SC		SC	
Kit Part Code			1L80		32591	
Kit Lot No.			16289LF00		076GCC-05	
Kit Exp. Date			11-Dec-12		08-Feb-13	
Kit Regulatory Status			FDA IVD		FDA IVD	

HBsAg<sup>1</sup> (s/co)

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	DiaSorin ETI-MAK-2 PLUS HBsAg	DiaSorin Liaison <sup>®</sup> HBsAg	Ortho VITROS HBsAg	Siemens ADVIA Centaur HBsAg
PHM937-01	6-Mar-07	0	0.2	Pending	0.1	0.2
PHM937-02	8-Mar-07	2	0.3	Pending	0.1	0.3
PHM937-03	15-Mar-07	9	1.0	Pending	1.2	1.1
PHM937-04	19-Mar-07	13	2.1	Pending	3.2	3.0
PHM937-05	22-Mar-07	16	5.0	Pending	8.6	6.3
Test Date			07-Aug-12		15-Aug-12	14-Aug-12
Test Site			SC		RL	RL
Kit Part Code			P001932		6801322	03393362
Kit Lot No.			0710330A		7250	93153167
Kit Exp. Date			08-Sep-12		03-Jan-13	25-Apr-13
Kit Regulatory Status			FDA IVD		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.

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 <sup>®</sup> TaqScreen MPX Test Result
PHM937-01	6-Mar-07	0	2.6 x 10 <sup>2</sup>	POS	2.3 x 10 <sup>2</sup>	Pending
PHM937-02	8-Mar-07	2	5.1 x 10 <sup>2</sup>	POS	7.2 x 10 <sup>2</sup>	Pending
PHM937-03	15-Mar-07	9	2.7 x 10 <sup>3</sup>	POS	3.7 x 10 <sup>3</sup>	Pending
PHM937-04	19-Mar-07	13	8.5 x 10 <sup>3</sup>	POS	1.3 x 10 <sup>4</sup>	Pending
PHM937-05	22-Mar-07	16	1.5 x 10 <sup>4</sup>	POS	2.9 x 10 <sup>4</sup>	Pending
Test Date			15-Aug-12	28-Aug-12	20-Aug-12	
Test Site			RL	RL	SC	
Kit Part Code			2N40-90	302573/302574	03577163 190	
Kit Lot No.			435090	607611	P17192	
Kit Exp. Date			27-Dec-12	15-Mar-14	31-Aug-13	
Kit Regulatory Status			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 (s/co)
PHM937-01	6-Mar-07	0	0.5	0.1	0.0	0.1	0.5
PHM937-02	8-Mar-07	2	0.5	0.1	0.0	0.1	0.5
PHM937-03	15-Mar-07	9	0.5	0.1	0.0	0.1	0.5
PHM937-04	19-Mar-07	13	0.6	0.1	0.0	0.3	0.5
PHM937-05	22-Mar-07	16	0.5	0.1	0.0	0.4	0.5
Test Date			7-Aug-12	7-Aug-12	7-Aug-12	8-Aug-12	8-Aug-12
Test Site			SC	SC	SC	SC	SC
Kit Part Code			8B88-20	6L23	P001931	P001930	P001929
Kit Lot No.			08372M500	07578LI00	0650320A	0600400B	0490470B
Kit Exp. Date			27-Jan-13	8-Nov-12	7-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