

OVERVIEW

HBV Seroconversion Panel PHM940 (genotype A) is an 8-member panel of undiluted, naturally occurring plasma samples, collected over 29 days in 2008 from a 48-year old male. No preservatives were added.

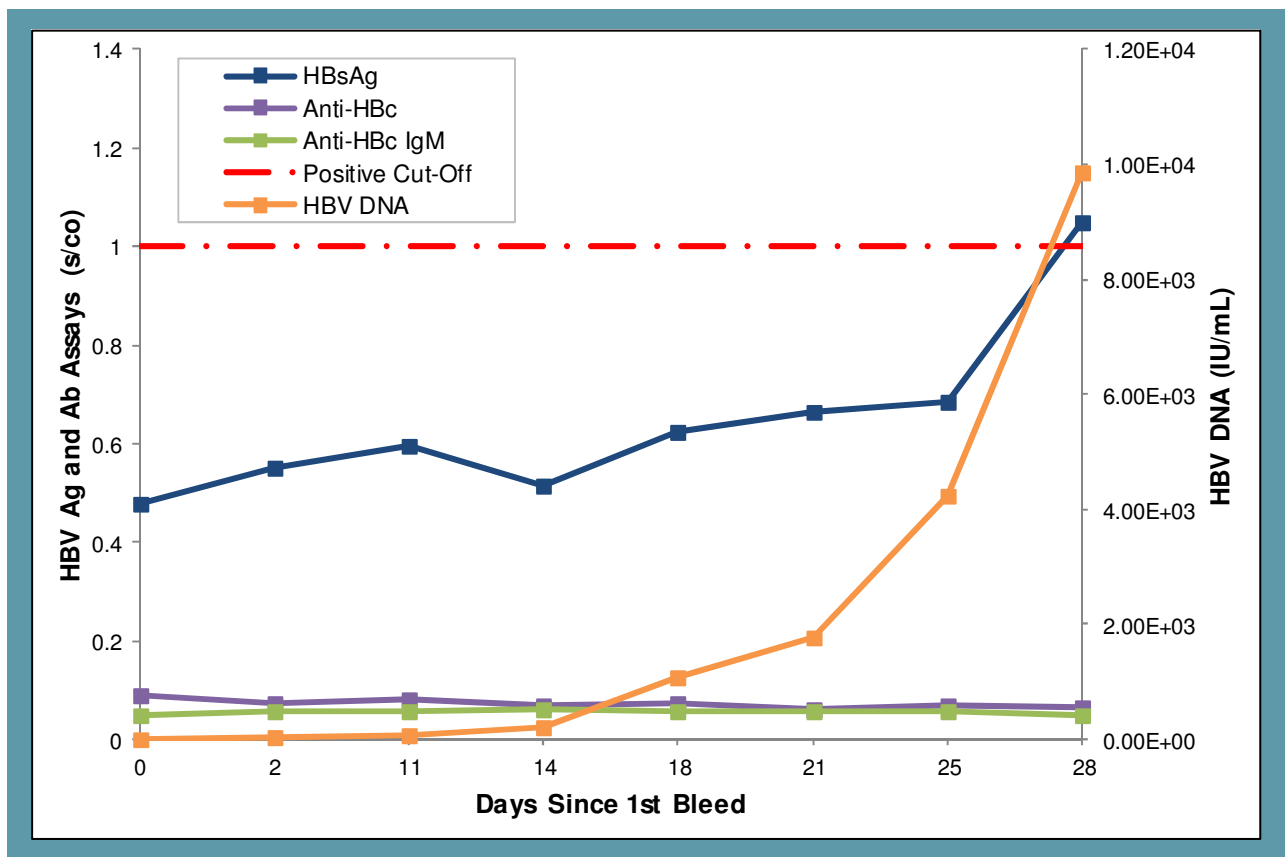
Test results from commercially-available HBV antigen, antibody, and DNA assays are included. This panel converts from negative to positive for hepatitis B surface antigen (HBsAg). All panel members are positive for HBV DNA and negative for HBV antibodies.

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.

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.

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 Abbott ARCHITECT HBV antibody and antigen test results and Roche COBAS® AmpliPrep/TaqMan® HBV DNA results.

DATA SHEET

HBsAg

Panel Member	Bleed Date	Days Since First Bleed	Abbott ARCHITECT HBsAg (s/co) ¹	Bio-Rad Genetic Systems™ HBsAg EIA (s/co) ¹	DiaSorin ETI-MAK-2 PLUS HBsAg (s/co) ¹
PHM940-01	25 Mar 08	0	0.480	0.292	0.114
PHM940-02	27 Mar 08	2	0.550	0.292	0.114
PHM940-03	05 Apr 08	11	0.595	0.545	0.250
PHM940-04	08 Apr 08	14	0.515	0.366	0.182
PHM940-05	12 Apr 08	18	0.625	0.545	0.341
PHM940-06	15 Apr 08	21	0.665	0.748	0.341
PHM940-07	19 Apr 08	25	0.685	0.604	0.273
PHM940-08	22 Apr 08	28	1.05	1.69	1.00
Test Date			10 Jul 13	10 Jul 13	08 Jul 13
Test Site			SC	SC	SC
Kit Part Code			1L80	32591	P001932
Kit Lot No.			24337LF00	3316cc-05	0710370A
Kit Exp. Date			11 Aug 13	23 Sep 13	13 Jul 13
Kit Regulatory Status			IVD	IVD	IVD/CE

¹Results are reported as the mean result of duplicate testing expressed as a signal to cut-off value (s/co). Results in red are considered positive/reactive.
SC = SeraCare
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

HBsAg

Panel Member	Bleed Date	Days Since First Bleed	Ortho VITROS HBsAg	Siemens ADVIA Centaur	bioMerieux VIDAS®	DiaSorin Liaison®
PHM940-01	25 Mar 08	0	NEG	PENDING	PENDING	PENDING
PHM940-02	27 Mar 08	2	NEG	PENDING	PENDING	PENDING
PHM940-03	05 Apr 08	11	NEG	PENDING	PENDING	PENDING
PHM940-04	08 Apr 08	14	NEG	PENDING	PENDING	PENDING
PHM940-05	12 Apr 08	18	NEG	PENDING	PENDING	PENDING
PHM940-06	15 Apr 08	21	NEG	PENDING	PENDING	PENDING
PHM940-07	19 Apr 08	25	NEG	PENDING	PENDING	PENDING
PHM940-08	22 Apr 08	28	NEG	PENDING	PENDING	PENDING
Test Date			10 Jul 13	NA	NA	NA
Test Site			RL	RL	RL	RL
Kit Part Code			NA	NA	NA	NA
Kit Lot No.			NA	NA	NA	NA
Kit Exp. Date			NA	NA	NA	NA
Kit Regulatory Status			IVD	IVD/CE	CE	CE

NEG = Negative; PENDING = Pending Results

NA = Not Available

RL = Reference Lab

IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

DATA SHEET

HBV DNA

Panel Member	Bleed Date	Days Since First Bleed	Abbott m2000 HBV (IU/mL)	Gen-Probe PROCLEIX ULTRIO	Roche Multiplex s201	Roche COBAS® AmpliPrep/TaqMan® (IU/mL)
PHM940-01	25 Mar 08	0	<15.0	POS	POS	<2.00 x 10 ¹
PHM940-02	27 Mar 08	2	<15.0	POS	POS	2.02 x 10 ¹
PHM940-03	05 Apr 08	11	3.50 x 10 ¹	POS	POS	6.56 x 10 ¹
PHM940-04	08 Apr 08	14	7.20 x 10 ¹	POS	POS	1.97 x 10 ²
PHM940-05	12 Apr 08	18	3.80 x 10 ²	POS	POS	1.09 x 10 ³
PHM940-06	15 Apr 08	21	6.44 x 10 ²	POS	POS	1.76 x 10 ³
PHM940-07	19 Apr 08	25	1.11 x 10 ³	POS	POS	4.24 x 10 ³
PHM940-08	22 Apr 08	28	3.63 x 10 ³	POS	POS	9.86 x 10 ³
Test Date			11 Jul 13	NA	NA	12 Jul 13
Test Site			RL	RL	RL	SC
Kit Part Code			NA	NA	NA	NA
Kit Lot No.			443490	1761520015	R07643	NA
Kit Exp. Date			20 Feb 14	15 Aug 14	31 Jan 14	NA
Kit Regulatory Status			IVD/CE	IVD/CE	IVD/CE	IVD/CE

POS = Positive
NA = Not Available
RL = Reference Lab; SC = SeraCare
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HBV Antibody and Other Tests

Panel Member	Bleed Date	Days Since First Bleed	Abbott ARCHITECT Core Total (s/co) ¹	Abbott ARCHITECT Core IgM (s/co) ¹	DiaSorin ETI-AB-AUK PLUS Anti-HBs (s/co) ¹	DiaSorin ETI-EBK PLUS HBeAg (s/co) ¹	DiaSorin ETI-AB-EBK PLUS Anti-HBe (co/s) ²
PHM940-01	25 Mar 08	0	0.0900	0.0500	0.0134	0.0417	0.545
PHM940-02	27 Mar 08	2	0.0750	0.0550	0.0134	0.0278	0.520
PHM940-03	05 Apr 08	11	0.0800	0.0550	0.00446	0.0278	0.499
PHM940-04	08 Apr 08	14	0.0700	0.0600	0.0223	0.0278	0.544
PHM940-05	12 Apr 08	18	0.0750	0.0550	0.0223	0.0694	0.573
PHM940-06	15 Apr 08	21	0.0600	0.0550	0.0268	0.0972	0.556
PHM940-07	19 Apr 08	25	0.0700	0.0550	0.0223	0.167	0.581
PHM940-08	22 Apr 08	28	0.0650	0.0500	0.0134	0.236	0.672
Test Date			15 Aug 13	10 Jul 13	05 Jul 13	09 Jul 13	08 Jul 13
Test Site			SC	SC	SC	SC	SC
Kit Part Code			6L22	6L23	P001931	P001930	P001929
Kit Lot No.			26417LI00	23495LI00	0650330B	0600440A/1	0490500A/1
Kit Exp. Date			25 Mar 14	06 Feb 14	04 Sep 13	31 Jul 13	31 Jul 13
Kit Regulatory Status			IVD	IVD	IVD/CE	IVD/CE	IVD/CE

¹Results are reported as the mean result of duplicate testing expressed as a signal to cut-off value (s/co).

²Results are reported as the mean result of duplicate testing expressed as a cut-off to signal value (co/s). Cut-off to signal value is inversely related to antibody reactivity.

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- ACCURUN® Quality Controls
- AccuType™ Viral Isolates
- SeraCon™ and Basematrix Processed Plasma

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

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

