

AccuVert™ HBV Seroconversion Panel

PHM937 (0605-0039) / Batch #10296522

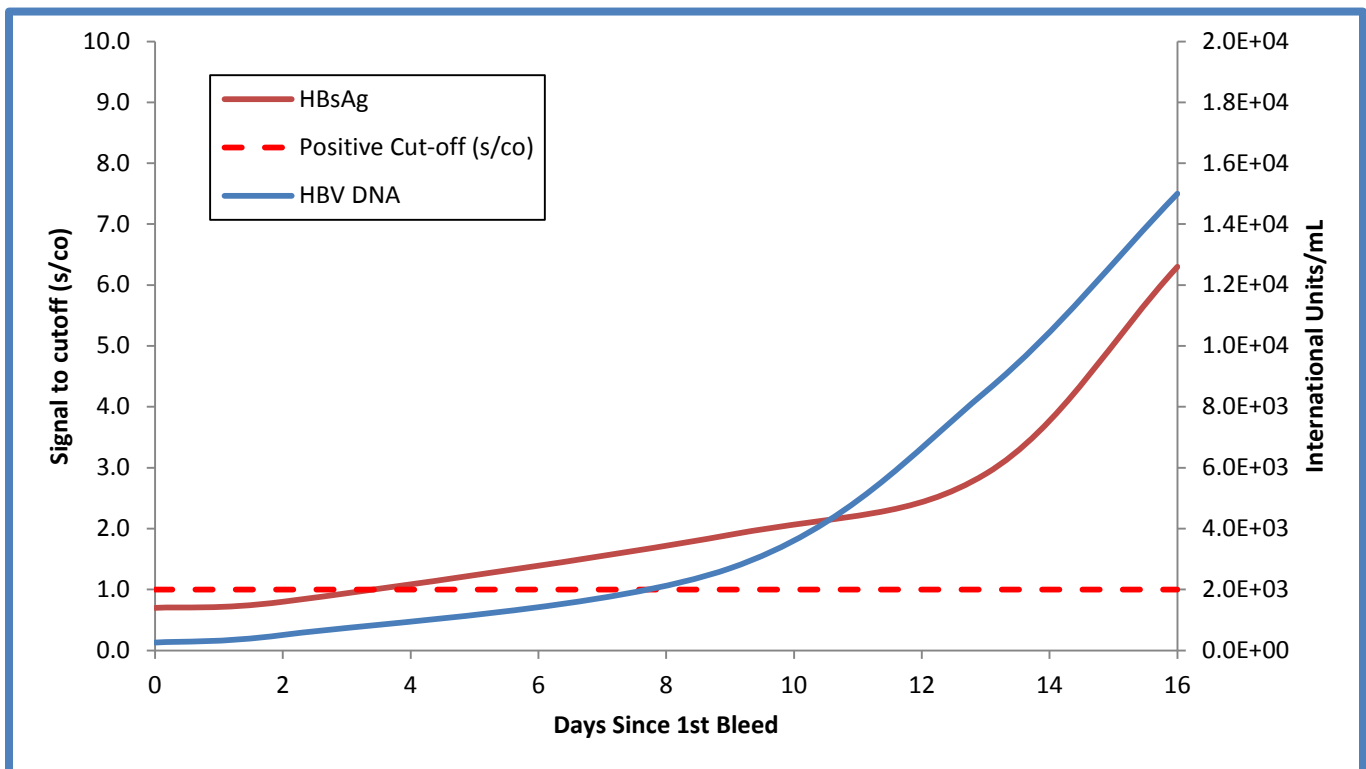
OVERVIEW

AccuVert™ HBV Seroconversion Panel PHM937 (0605-0039) / Batch #10296522 is a five member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL) from a genotype A donor. Panel members represent serial bleeds 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.

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 HBsAg; all were found negative for anti-HIV and anti-HCV. This does not ensure the absence of these or other human pathogens.

Evolution of HBV Markers in Early Infection



This graph demonstrates the evolution of early HBV infection amongst panel members from the Abbott Realtime HBV m2000 and Abbott ARCHITECT HBsAg test methods.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Days Since 1 st Bleed
01	BM217352	BD104066	06-Mar-07	0
02	BM217353	BD104066	08-Mar-07	2
03	BM217354	BD104066	15-Mar-07	9
04	BM217355	BD104066	19-Mar-07	13
05	BM217356	BD104066	22-Mar-07	16

HBV DNA

Panel Member	Abbott Realtime HBV m2000 (IU/mL) ¹	Roche HBV DNA CAP/CTM v.2.0 (IU/mL) ¹	Gen-Probe PROCLEIX ULTRIO Result
01	2.6 x 10²	2.3 x 10²	POS
02	5.1 x 10²	7.2 x 10²	POS
03	2.7 x 10³	3.7 x 10³	POS
04	8.5 x 10³	1.3 x 10⁴	POS
05	1.5 x 10⁴	2.9 x 10⁴	POS
Test Date	15-Aug-12	20-Aug-12	28-Aug-12
Test Site	RL	SC	RL
Kit Part Code	2N40-90	03577163 190	302573/302574
Kit Lot No.	435090	P17192	607611
Kit Exp. Date	27-Dec-12	31-Aug-13	15-Mar-14
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE

¹Results are reported in international units per mL (IU/mL); positive/reactive results are noted in bold red.

POS = Positive

RL = Reference Lab; SC = SeraCare Life Sciences

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

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HBsAg¹ (s/co)

Panel Member	Abbott ARCHITECT HBsAg Qualitative (s/co) ¹	Bio-Rad Genetic Systems™ HBsAg EIA 3.0 (s/co) ¹	DiaSorin ETI-MAK-2 PLUS HBsAg (s/co) ¹	Ortho Vitros HBsAg (s/co) ¹	Siemens ADVIA Centaur HBsAg (s/co) ¹
01	0.7	0.3	0.2	0.1	0.2
02	0.8	0.5	0.3	0.1	0.3
03	1.9	1.4	1.0	1.2	1.1
04	2.9	3.0	2.1	3.2	3.0
05	6.3	6.1	5.0	8.6	6.3
Test Date	07-Aug-12	08-Aug-12 22-Aug-12	07-Aug-12	15-Aug-12	14-Aug-12
Test Site	SC	SC	SC	RL	RL
Kit Part Code	1L80	32591	P001932	6801322	03393362
Kit Lot No.	16289LF00	076GCC-05	0710330A	7250	93153167
Kit Exp. Date	11-Dec-12	08-Feb-13	08-Sep-12	03-Jan-13	25-Apr-13
Kit Regulatory Status	IVD	IVD	IVD	IVD	IVD/CE

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

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Other HBV Tests

Panel Member	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 (s/co) ¹
01	0.1	0.0	0.1	0.5
02	0.1	0.0	0.1	0.5
03	0.1	0.0	0.1	0.5
04	0.1	0.0	0.3	0.5
05	0.1	0.0	0.4	0.5
Test Date	07-Aug-12	07-Aug-12	08-Aug-12	08-Aug-12
Test Site	SC	SC	SC	SC
Kit Part Code	6L23	P001931	P001930	P001929
Kit Lot No.	07578LI00	0650320A	0600400B	0490470B
Kit Exp. Date	08-Nov-12	07-Feb-13	26-Feb-13	29-Jan-13
Kit Regulatory Status	IVD	IVD	IVD	IVD

¹Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co).

SC = SeraCare

IVD = In Vitro Diagnostic

The package insert for this panel 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