

AccuVert™ HBV Seroconversion Panel

PHM941(M) 0605-0061 / Batch #10249283

OVERVIEW

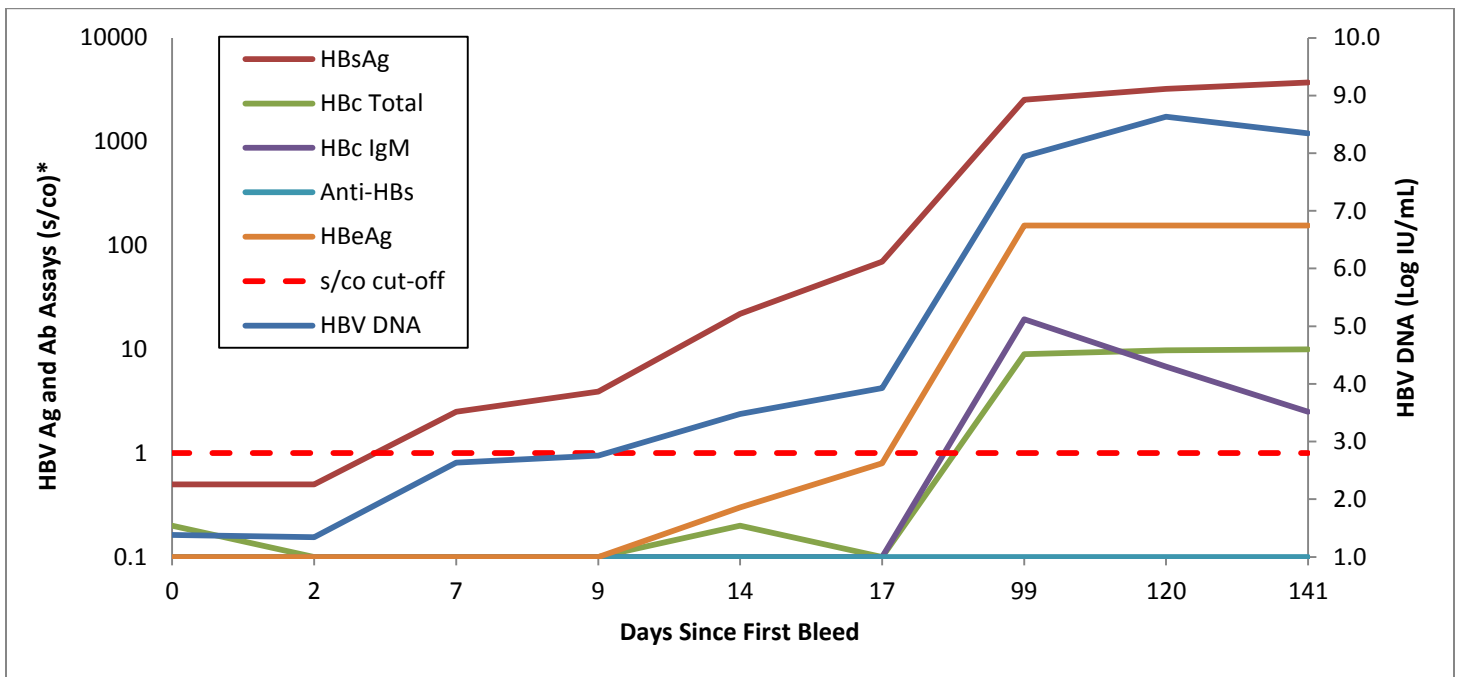
AccuVert™ HBV Seroconversion Panel PHM941(M), 0605-0061 is a 7-member modified panel originating from the 9-member HBV Seroconversion panel PHM941, 0605-0060. Members 04 and 06 from the original panel are no longer available. This panel is made of undiluted, naturally occurring plasma samples, collected over 142 days in 2008 from a 43-year old female and characterized as genotype A. 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), hepatitis B envelope antigen (HBeAg), anti-HBc (core total), and anti-HBc IgM (core IgM). All panel members are positive for HBV DNA.

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-1/2 and anti-HCV.

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This graph demonstrates the evolution of early HBV infection, illustrated with the Abbott m2000 HBV DNA, Abbott ARCHITECT HBsAg, HbC Total, HbC IgM assays, and DiaSorin Anti-HBs and HBeAg test methods.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed date	Days Since First Bleed
01	9229670	BD106646	08-Apr-2008	0
02	9229671	BD106646	10-Apr-2008	2
03	9229672	BD106646	15-Apr-2008	7
04	9229673	BD106646	17-Apr-2008	9
05	9229674	BD106646	22-Apr-2008	14
06	9229675	BD106646	25-Apr-2008	17
07	9230606	BD106646	16-Jul-2008	99
08	9231427	BD106646	06-Aug-2008	120
09	9232141	BD106646	27-Aug-2008	141

Members 04 and 06 from PHM941 are no longer available, data provided for informational purposes only.

HBV DNA

Panel Member	Abbott m2000 HBV DNA (IU/mL)	Gen-Probe PROCLEIX ULTRIO	Roche Multiplex S201	Roche COBAS® AmpliPrep / TaqMan® (IU/mL)
01	2.4×10^1	POS	POS	4.8×10^1
02	2.2×10^1	POS	POS	3.8×10^1
03	4.4×10^2	POS	POS	5.7×10^2
04	5.7×10^2	POS	POS	7.8×10^2
05	3.0×10^3	POS	POS	5.6×10^3
06	8.5×10^3	POS	POS	1.4×10^4
07	8.8×10^7	POS	POS	5.9×10^7
08	4.3×10^8	POS	POS	$>1.7 \times 10^8$
09	2.2×10^8	POS	POS	$>1.7 \times 10^8$
Test Date	30-Jul-2013	NA	NA	29-Jul-2013
Test Site	RL	RL	RL	SC
Kit Part Code	NA	NA	NA	5027012190
Kit Lot No.	NA	615200	R07643	R13006
Kit Exp. Date	NA	15-Aug-2014	31-Jan-2014	31-Jul-2014
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE	IVD/CE

Results in bold red are considered positive/reactive.

NA = Not Available; POS = Positive

RL = Reference Lab; SC = SeraCare

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

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HBsAg

Panel Member	Abbott ARCHITECT HBsAg (s/co) ¹	Bio-Rad Genetic Systems™ HBsAg EIA (s/co) ¹	DiaSorin ETI-MAK-2 PLUS HBsAg (s/co) ¹	Siemens ADVIA Centaur HBsAg	Ortho VITROS HBsAg
01	0.5	0.4	0.2	NEG	NEG
02	0.5	0.6	0.2	NEG	NEG
03	2.5	1.7	0.9	POS	NEG
04	3.9	2.4	1.5	POS	POS
05	21.9	11.0	7.4	POS	POS
06	69.7	20.3	21.0	POS	POS
07	2540	>81.3	232	POS	POS
08	3220	>81.3	232	POS	POS
09	3720	>81.3	232	POS	POS
Test Date	27-Aug-2013	25-Jul-2013 30-Jul-2013	26-Jul-2013	02-Aug-2013	01-Aug-2013
Test Site	SC	SC	SC	RL	RL
Kit Part Code	1L80	32591	P001932	NA	NA
Kit Lot No.	29248LF00	331GCC-05 362GCC-05	0710380A	NA	NA
Kit Exp. Date	10-Jan-2014	23-Sep-2013 30-Nov-2013	27-Oct-2013	NA	NA
Kit Regulatory Status	IVD	IVD	IVD/CE	IVD/CE	IVD

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

Results in bold red are considered positive/reactive.

NA = Not Available; POS = Positive; NEG = Negative

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HBV Antibody and Other Tests

Panel Member	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-AB-AUK PLUS HBeAg (s/co) ¹	DiaSorin ETI-AB-AUK PLUS Anti-HBe (co/s) ²
01	0.2	0.1	0.1	0.1	0.6
02	0.1	0.1	0.1	0.1	0.5
03	0.1	0.1	0.1	0.1	0.5
04	0.1	0.1	0.1	0.1	0.6
05	0.2	0.1	0.1	0.3	0.5
06	0.1	0.1	0.1	0.8	0.6
07	9.0	19.5	0.1	156	0.1
08	9.8	6.8	0.1	156	0.1
09	10.0	2.5	0.1	156	0.1
Test Date	15-Aug-2013	15-Aug-2013	24-Jul-2013	18-Sep-2013	26-Jul-2013
Test Site	SC	SC	SC	SC	SC
Kit Part Code	6L22	6L23	P001931	P001930	P001929
Kit Lot No.	26417LI00	23495LI00	0650330B	0600450A	0490510A/2
Kit Exp. Date	25-Mar-2014	25-Mar-2014	04-Sep-2013	28-Feb-2014	30-Jan-2014
Kit Regulatory Status	IVD	IVD	IVD	IVD/CE	IVD/CE

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

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

Results in bold red are considered positive/reactive.

SC = SeraCare

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

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