

AccuVert™ HBV Seroconversion Panel

PHM940 (0605-0059) / Batch #10349348

OVERVIEW

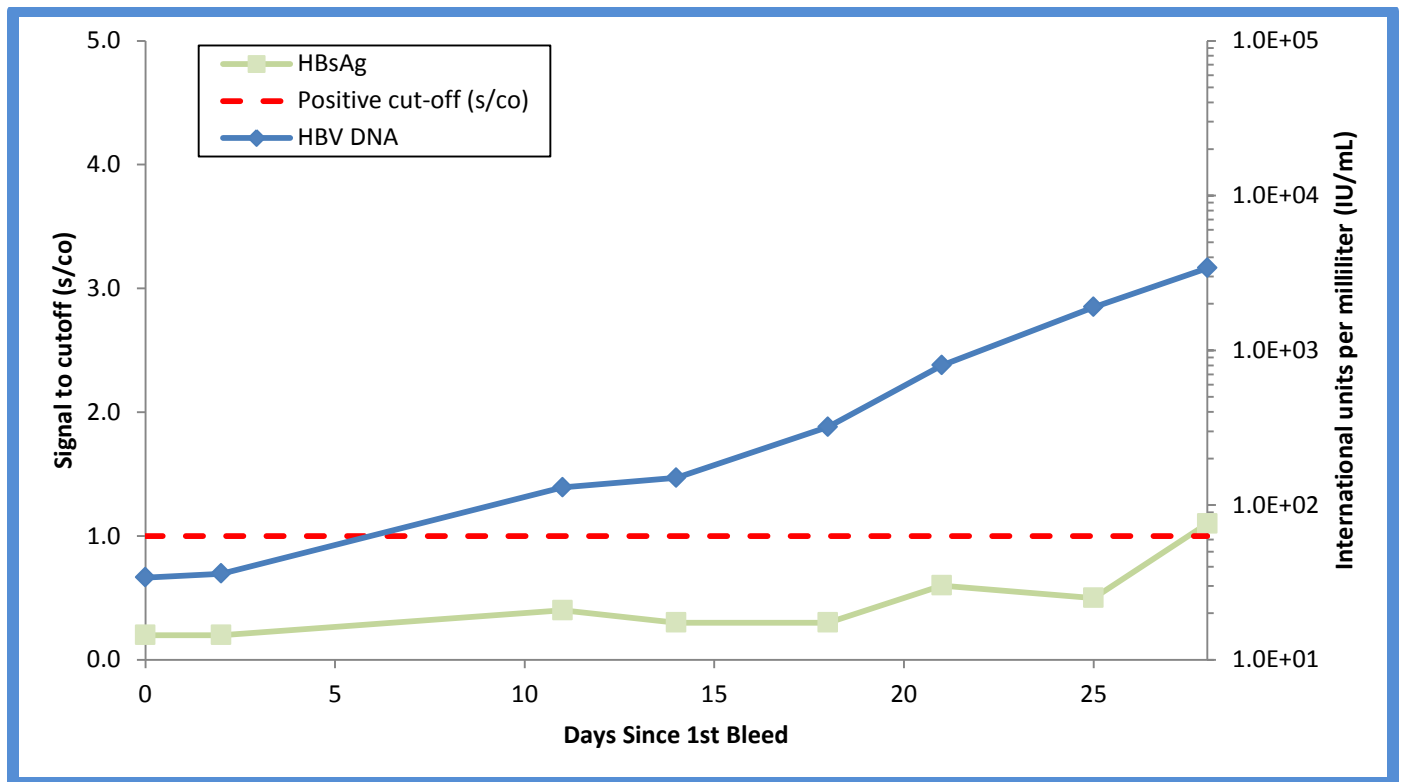
AccuVert™ HBV Seroconversion Panel PHM940 (0605-0059) / Batch #10349348 is an 8-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL) collected over 28 days in 2008 from a 48-year old male characterized as genotype B. No preservatives were added.

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

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and found negative for anti-HIV-1/2 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 m2000 (HBV DNA) and Bio-Rad GS HBsAg EIA 3.0 (HBsAg) test methods.

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Panel Member Information

Panel Member	SeraCare Batch #	Bleed Date	Days Since 1 st Bleed
01	9229244	25-Mar-2008	0
02	9229245	27-Mar-2008	2
03	9229246	05-Apr-2008	11
04	9229247	08-Apr-2008	14
05	9229248	12-Apr-2008	18
06	9229249	15-Apr-2008	21
07	9229250	19-Apr-2008	25
08	9229251	22-Apr-2008	28

HBV DNA and HBsAg Neutralization

Panel Member	Abbott RealTime m2000 HBV assay (IU/mL) ^{1,3}	Roche COBAS® AmpliPrep/COBAS TaqMan® HBV Test, v 2.0 (IU/mL) ^{1,3}	Gen-Probe Procleix Ultrio Plus assay (s/co) ²	ABBOTT PRISM HBsAg Confirmatory (s/co) ^{2,3}
01	3.4 x 10¹	24, <20^A	14.3	0.4
02	3.6 x 10¹	<20	14.5	0.4
03	1.3 x 10²	9.6 x 10¹	14.4	0.6
04	1.5 x 10²	2.0 x 10²	13.9	0.4
05	3.2 x 10²	4.3 x 10²	13.9	0.4
06	8.0 x 10²	1.6 x 10³	13.8	0.6
07	1.9 x 10³	5.4 x 10³	14.1	0.8
08	3.4 x 10³	6.9 x 10³	14.3	1.2
Test Date	02-Jul-2018	28-Jun-2018	11-Jul-2018	29-Jun-2018
Test Site	RL	RL	RL	RL
Kit Part Code	NA	NA	NA	NA
Kit Lot No.	NA	Y2668100000	171794981511188	NA
Kit Exp. Date	NA	30-Jun-2019	15-Nov-2018	NA
Kit Regulatory Status	IVD	IVD/CE	IVD	IVD

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

²Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

³Results are reported as the mean result of duplicate testing.

^AResults of duplicate run reported independently.

NA = Not Available

RL = Reference Lab; IVD = In Vitro Diagnostic

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HBsAg

Panel Member	Abbott ARCHITECT HBsAg Qualitative assay (s/co) ^{1,2}	Bio-Rad GS HBsAg EIA 3.0 (s/co) ^{1,2}	Roche Elecsys HBsAg assay (s/co) ^{1,2}	Siemens ADVIA Centaur HBsAg assay (s/co) ^{1,2}
01	0.2	0.2	0.6	<0.10
02	0.2	0.2	0.6	<0.10
03	0.2	0.4	0.6	<0.10
04	0.2	0.3	0.6	<0.10
05	0.2	0.3	0.7	<0.10
06	0.3	0.6	0.8	<0.10
07	0.3	0.5	0.7	0.12, <0.10 ^A
08	0.4	1.1	1.0	0.3
Test Date	28-Jun-2018	29-Jun-2018	06-Jul-2018	27-Jun-2018
Test Site	SC	SC	RL	RL
Kit Part Code	4P54	32591	NA	NA
Kit Lot No.	83418FN00	108NCC-05	NA	NA
Kit Exp. Date	18-Sep-2018	28-Feb-2019	NA	NA
Kit Regulatory Status	IVD	IVD/CE	IVD	IVD

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

^AResults of duplicate run reported independently.

NA = Not available

SC = SeraCare; RL = Reference Lab; 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.