

OVERVIEW

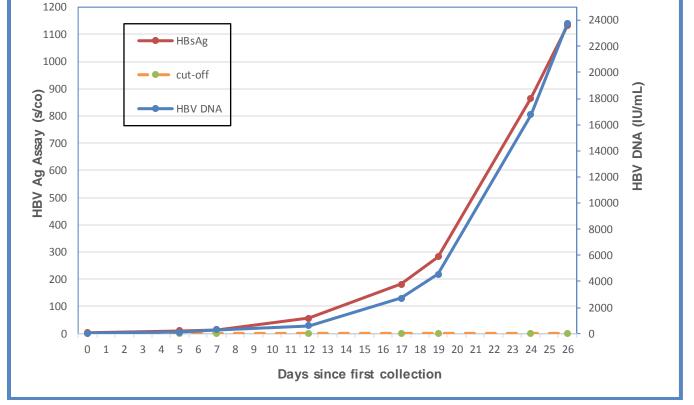
AccuVert[™] HBV Seroconversion Panel PHM936, 0605-0038 (Batch #10564204) is an 8-member HBV Seroconversion panel. This Data Sheet contains test results specific for HBV Seroconversion Panel PHM936, genotype A. PHM936 is an eight member series collected from a single individual over 26 days in 2000.

Member 1 challenges the sensitivity of the seven HBsAg methods and the two HBV DNA methods tested. Member 4 represents a low-titer HBeAg sample.

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 HBV DNA and 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.



AccuVert[™] HBV Seroconversion Panel

This graph demonstrates the evolution of early HBV infection, illustrated with test results over time for different analytes. Assays plotted here: Roche cobas AmpliPrep/TaqMan 2.0 HBV DNA and Abbott ARCHITECT HBsAg test methods.

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13850-01 August 2021



Panel Member Information

Panel Member	Collection Date	Days Since 1 st Collection
01	19-May-2000	0
02	24-May-2000	5
03	26-May-2000	7
04	31-May-2000	12
05	05-Jun-2000	17
06	07-Jun-2000	19
07	12-Jun-2000	24
08	14-Jun-2000	26

HBV DNA

Panel Member	Abbott REALTIME HBV DNA m2000 [®] (IU/mL) ^{1,2}	COBAS [®] AmpliPrep / COBAS TaqMan [®] (IU/mL) ^{1,2}
01	46	38
02	159	109
03	269	288
04	545	593
05	1485	2716
06	2884	4551
07	8676	16743
08	11173	23751
Test Date	10 Jun 2021	18 Jun 2021
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	517467	G26335
Kit Exp. Date	11 Jun 2022	31 Dec 2021

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

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

RL = Reference Lab; NA = Not Available



HBsAg

Panel Member	Abbott ARCHITECT HBsAg Qualitative (s/co) ^{1,2}	Abbott Alinity i HBsAg (s/co) ^{1,2}	Ortho HBsAg VITROS EC (s/co) ^{1,2}	Bio-Rad Genetic Systems [™] HBsAg EIA (s/co) ^{1,2}
01	3.3	0.8	0.7	1.8
02	9.9	2.7	2.9	4.3
03	14.6	7.8	4.4	6.3
04	56.1	32.8	20.7	20.6
05	181.5	80.0	68.2	38.2
06	283.1	105.4	113.0	40.7
07	864.5	687.1	329.0	>42.1 ³
08	1132.2	887.4	464.0	>42.1 ³
Test Date	17 Jun 2021	16 Jun 2021	16 Jun 2021	15 Jun 2021
Test Site	SC	RL	RL	SC
Kit Part Code	4P53	NA	NA	32591
Kit Lot No.	24362FN00	25130FN00	8840	175QCC-05
Kit Exp. Date	28 Sep 2021	23 Oct 2021 2020	14 Feb 2022	31 Aug 2021

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

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

³Result is off scale.

SC = SeraCare; RL= Reference Lab; NA = Not Available

HBsAg

Panel Member	DiaSorin LIAISON XL HBsAg (S/CO) ^{1,2}	Roche COBAS 6000 HBsAg Elecsys (COI) ^{1,2}	Siemens HBsAg Advia Centaur (INDEX) ^{1,2}
01	1.0	1.5	3.1
02	2.7	4.3	10.7
03	3.2	5.8	14.5
04	12.6	21.7	58.5
05	38.7	69.4	215.1
06	60.3	125.7	344.4
07	202.0	360.5	>1000 ³
08	272.0	471.2	>1000 ³
Test Date	21 Jun 2021	16 Jun 2021	16 Jun 2021
Test Site	SC	RL	RL
Kit Part Code	318250	NA	NA
Kit Lot No.	277022	505840	251
Kit Exp. Date	10 Jun 2022	31 Jul 2021	24 Mar 2022

¹Results are reported as INDEX, S/CO, or COI (cut off Index); positive/reactive results are noted in bold red.

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

SC = SeraCare; RL= Reference Lab; NA = Not Available

³Result is off scale.



HBeAg

Panel Member	DiaSorin LIAISON XL HBeAg (INDEX) ^{1,2}
01	0.2
02	0.2
03	0.2
04	1.0 , 0.8 ³
05	4.2
06	4.7
07	15.9
08	20.2
Test Date	16 Jun 2021
Test Site	SC
Kit Part Code	318150
Kit Lot No.	267005
Kit Exp. Date	22 Nov 2021

¹Results are reported as INDEX; positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing, except where noted.

³Individual replicate results are reported.

SC = SeraCare

The package insert for this panel can be found at <u>www.seracare.com</u>.

A printed copy of the package insert or data sheet may be requested by email at <u>CDx-Info@LGCGroup.com</u> or by phone at 508.244.6400.