AccuSet™ HBV DNA Genotype Performance Panel

0805-0362 / Batch #10387873

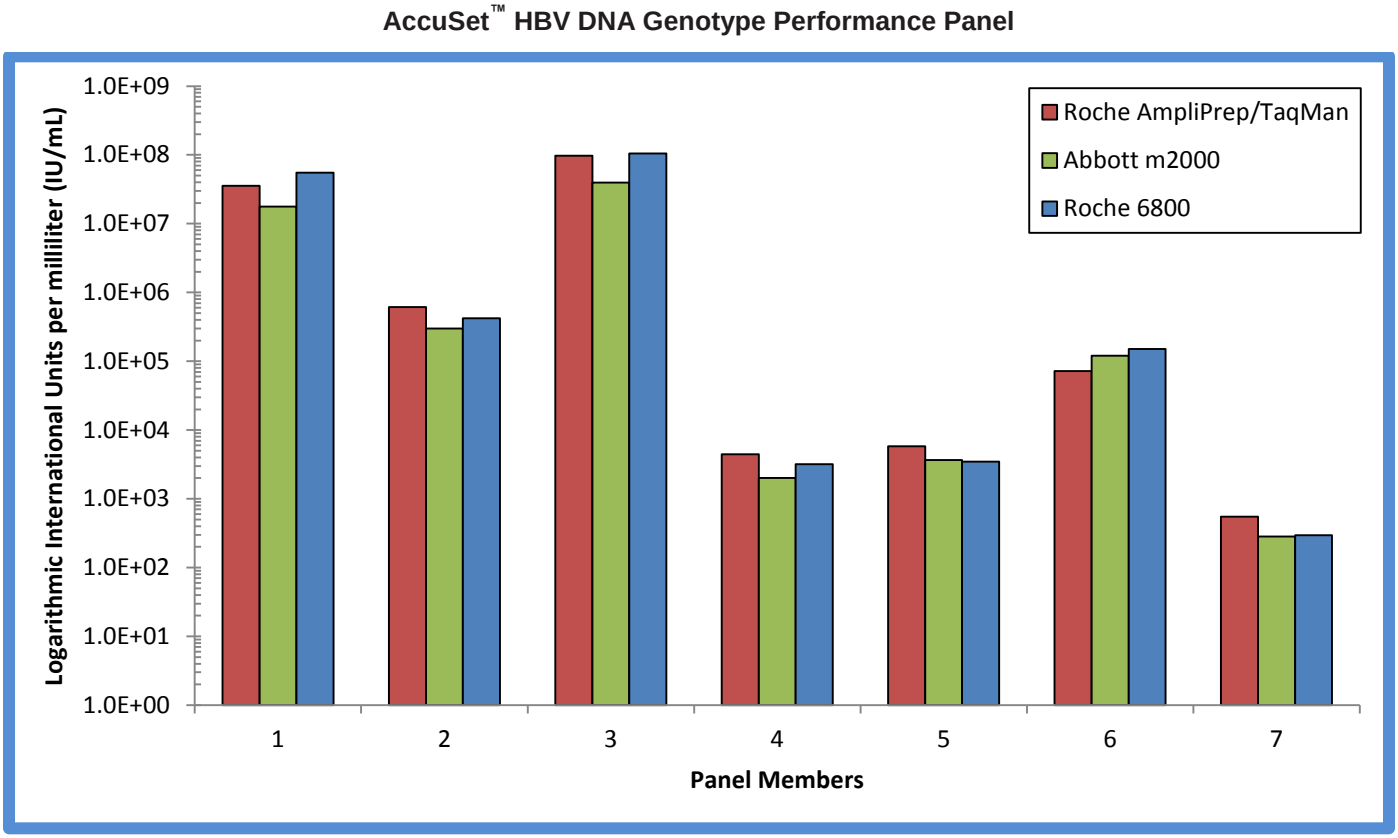
OVERVIEW

AccuSet™ HBV DNA Genotype Performance Panel (0805-0362) is a 7-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL per vial). Each panel member represents a specific HBV genotype which has been collected from an individual donor positive for HBV. Each sample represents a single collection event. No preservatives were added.

This panel of human plasma samples demonstrates a diverse collection of HBV genotypes A, B, C, D, E, F and H. Test results from commercially-available HBV genotype, antigen, and antibody assays are included for characterization of the panel members.

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. All panel members were found positive for HBV DNA. 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.



This graph demonstrates HBV DNA reactivity amongst panel members utilizing test results from the Roche AmpliPrep/TaqMan, Abbott m2000, and Roche 6800.

AccuSet™ HBV DNA Genotype Performance Panel

0805-0362 / Batch #10387873

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	HBV Genotype[1]
01	9231138	BD106708	29-May-2008	A
02	10375800	NA	22-Mar-2017	B
03	10375805	NA	30-May-2017	C
04	9249006	BD110366	29-Oct-2010	D
05	9259412	BD111374	21-Mar-2012	E
06	10034177	BD201352	31-Mar-2008	F
07	9268233	BD200005	03-Aug-2011	H

[1]Genotypes were classified at regional reference labs using commercially available HBV DNA sequencing methods.
NA = Not Available

HBV DNA

Panel Member	Roche 6800 cobas® HBV (IU/mL)[1,2]	Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0 (IU/mL)[1]	Abbott m2000 RealTi*me* HBV (IU/mL)[1]
01	**5.5E+07**	**3.6E+07**	**1.8E+07**
02	**4.2E+05**	**6.2E+05**	**3.0E+05**
03	**1.0E+08**	**9.7E+07**	**4.0E+07**
04	**3.2E+03**	**4.4E+03**	**2.0E+03**
05	**3.5E+03**	**5.8E+03**	**3.6E+03**
06	**1.5E+05**	**7.2E+04**	**1.2E+05**
07	**3.0E+02**	**5.5E+02**	**2.8E+02**
Test Date	14-Jan-2019	21-Jan-2019	21-Jan-2019
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	NA	E1477500000	NA
Kit Exp. Date	NA	29-Feb-2020	NA
Kit Regulatory Status	IVD/CE	IVD	IVD

[1]Results are reported as International Units per mL (IU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as the mean result of duplicate testing.
RL = Reference Lab
NA = Not Available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

AccuSet™ HBV DNA Genotype Performance Panel

0805-0362 / Batch #10387873

HBsAg, HBeAg, Anti-HBc, and Anti-HBe

Panel Member	Abbott ARCHITECT HBsAg (s/co)[1,4]	Bio-Rad GS HBsAg EIA 3.0 (s/co)[1,4]	Abbott ARCHITECT HBeAg (TV)[2,4]	DiaSorin ETI-AB-COREK PLUS Anti-HBc EIA (co/s)[3,4]	DiaSorin ETI-AB-EBK Plus Anti-HBe EIA (co/s)[3,4]
01	**7454.1**	**29.0***	**1027.0**	**233.0**	0.1
02	**5566.5**	**29.0***	0.3	**233.0**	**259.0**
03	**1322.4**	**29.0***	**1569.1**	**174.8**	0.1
04	**5335.5**	**29.0***	0.3	**233.0**	**215.8**
05	**3840.3**	**29.0***	0.3	**233.0**	**172.7**
06	**535.2**	**29.0***	3.7	0.3	0.3
07	**5862.1**	**29.0***	0.4	**155.3**	**518.0**
Test Date	14-Jan-2019	15-Jan-2019	04-Feb-2019	14-Jan-2019	11-Jan-2019
Test Site	SC	SC	RL	SC	SC
Kit Part Code	4P54	32591	NA	P001927	P001929
Kit Lot No.	91259FN00	171NCC-05	92369LI00	9910670A	0490730AA
Kit Exp. Date	03-May-2019	31-Jul-2019	17-Jul-2019	07-Mar-2019	27-Mar-2019
Kit Regulatory Status	IVD/CE	IVD	IVD/CE	IVD	IVD

[1]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as a Test Value (TV); positive/reactive results are noted in bold red.
[3]Results are reported as a cutoff to signal ratio (co/s); positive/reactive results are noted in bold red.
[4]Results are reported as the mean result of duplicate testing.
*Results are off-scale.
SC = SeraCare; RL = Reference Lab
NA = Not Available
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.