

AccuSet™ HBV Worldwide Performance Panel

0805-0313 / Batch #10294850

OVERVIEW

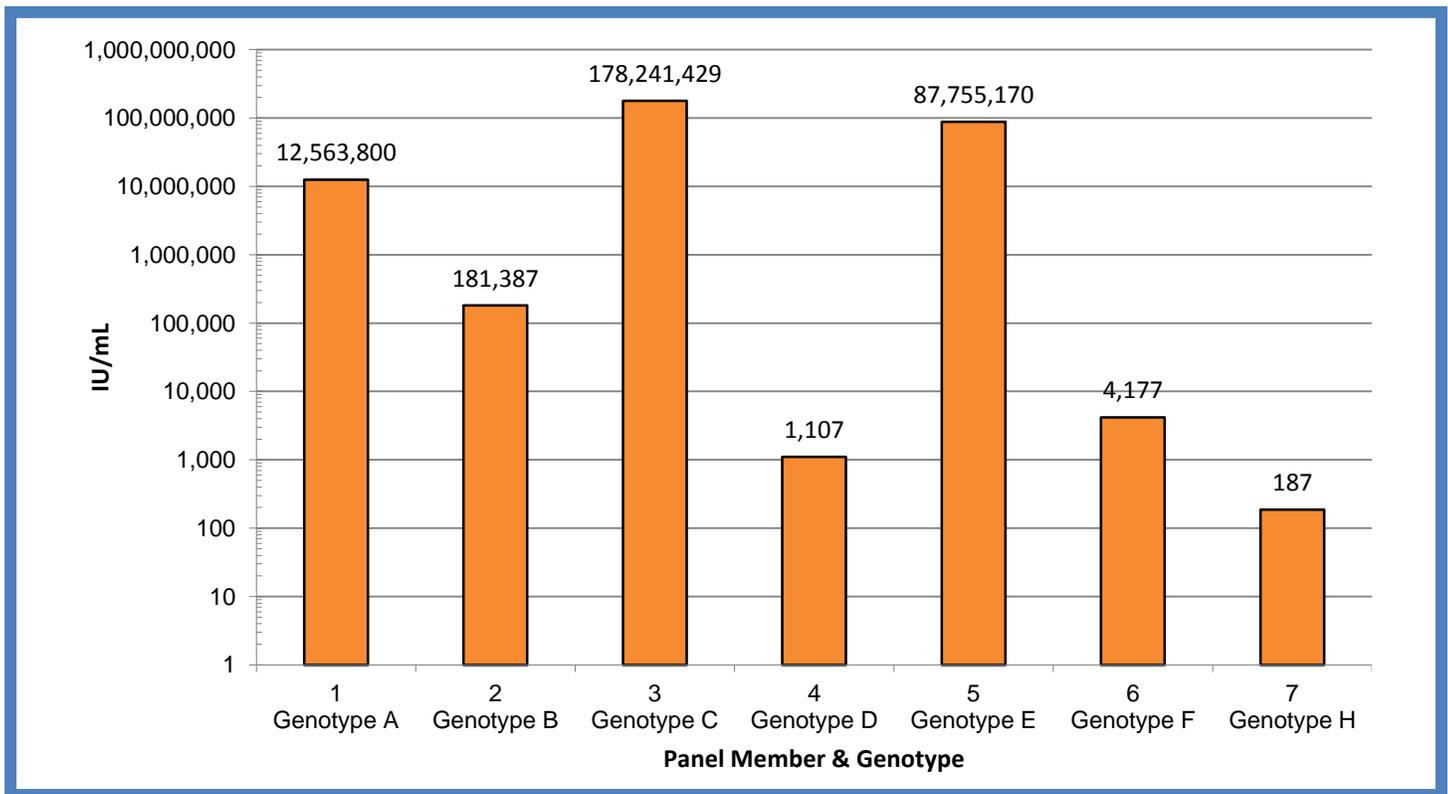
AccuSet™ HBV Worldwide Performance Panel 0805-0313 / Batch #10294850 is a 7-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent bleeds from multiple individuals positive for a variety of HBV genotypes. Each sample represents 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, DNA, antigen, and antibody assays are included for characterization of each panel member.

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. 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.

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This graph demonstrates HBV DNA reactivity amongst panel members utilizing test results from the Abbott m2000 (IU/mL) test method.

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Panel Member Information

Panel Member	SeraCare Batch #	Donor ID	Bleed Date	Genotype
01	9231138	BD106708	29-May-2008	A
02	10071449	NA	NA	B
03	9189946	NA	NA	C
04	9249006	BD110366	29-Oct-2010	D
05	9214356	BD104501	08-Mar-2007	E
06	10034178	BD201353	04-Sep-2009	F
07	9268233	BD200005	03-Aug-2011	H

NA = Not Available

HBV DNA

Panel Member	Roche COBAS® AmpliPrep COBAS® TaqMan HBV Test v2.0 (IU/mL) ¹	Abbott m2000 RealTime HBV (IU/mL) ¹
01	9,874,459	12,563,800
02	267,620	181,387
03	>170,000,000	178,241,429
04	1,031	1,107
05	41,855,315	87,755,170
06	4,536	4,177
07	83	187
Test Date	17-Oct-2017	23-Oct-2017
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	NA	NA
Kit Exp. Date	NA	NA
Kit Regulatory Status	CE, IVD	IVD

¹ Quantitative HBV DNA results are the means of duplicates expressed as International Units/mL. Members considered reactive are noted in bold red.

RL = Reference Lab; NA = Not Available

CE = Conformité Européenne or CE Marking; IVD = In vitro diagnostic use

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HBsAg and HBeAg

Panel Member	Abbott ARCHITECT HBsAg (s/co) ¹	Ortho VITROS® HBsAg (s/co) ¹	Abbott ARCHITECT HBeAg (s/co) ¹	DiaSorin ETI-EBK PLUS HBeAg (s/co) ¹
01	6897.8	6445.0	630.2	61.5
02	4221.8	2865.0	52.5	61.5
03	1834.0	1105.0	1170.5	61.5
04	5468.6	7950.0	0.3	0.0
05	2653.2	1935.0	0.6	0.1
06	29.7	12.4	0.4	0.5
07	5619.5	5185.0	0.3	0.1
Test Date	16-Oct-2017	18-Oct-2017	01-Nov-2017	19-Oct-2017
Test Site	SC	RL	RL	SC
Kit Part Code	4P54	NA	NA	P001930
Kit Lot No.	77240FN00	NA	73324LI00	0600610AB
Kit Exp. Date	22-Feb-2018	NA	21-Nov-2017	10-Apr-2018
Kit Regulatory Status	CE, IVD	CE, IVD	CE, IVD	IVD

¹ Immunoassay 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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HBV Antibody

Panel Member	DiaSorin ETI-CORE-IgMK PLUS Anti-HBc IgM (s/co) ¹	DiaSorin ETI-AB-COREK PLUS Anti-HBc (co/s) ²	DiaSorin ETI-AB-EBK PLUS Anti-HBe (co/s) ²	DiaSorin ETI-AB-AUK PLUS Anti-HBs (s/co) ¹
01	0.8	297.0	0.2	0.0
02	0.2	297.0	0.2	0.0
03	0.1	4.1	0.2	0.0
04	0.2	297.0	61.7	0.2
05	0.4	297.0	69.2	0.0
06	0.1	0.2	0.4	0.0
07	1.9	297.0	147.6	0.3
Test Date	17-Oct-2017	20-Oct-2017	19-Oct-2017	19-Oct-2017
Test Site	SC	SC	SC	SC
Kit Part Code	P001928	P001927	P001929	P001931
Kit Lot No.	0270440A	9910650A	0490680A	0650430A
Kit Exp. Date	31-Jan-2018	28-Mar-2018	15-Apr-2018	31-Jan-2018
Kit Regulatory Status	IVD	IVD	IVD	IVD

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.

²Immunoassay results are means of duplicates expressed as cutoff to signal ratios (co/s). Ratios ≥ 1.0 are considered reactive and noted in bold red.

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IVD = In vitro diagnostic use

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.