

## OVERVIEW

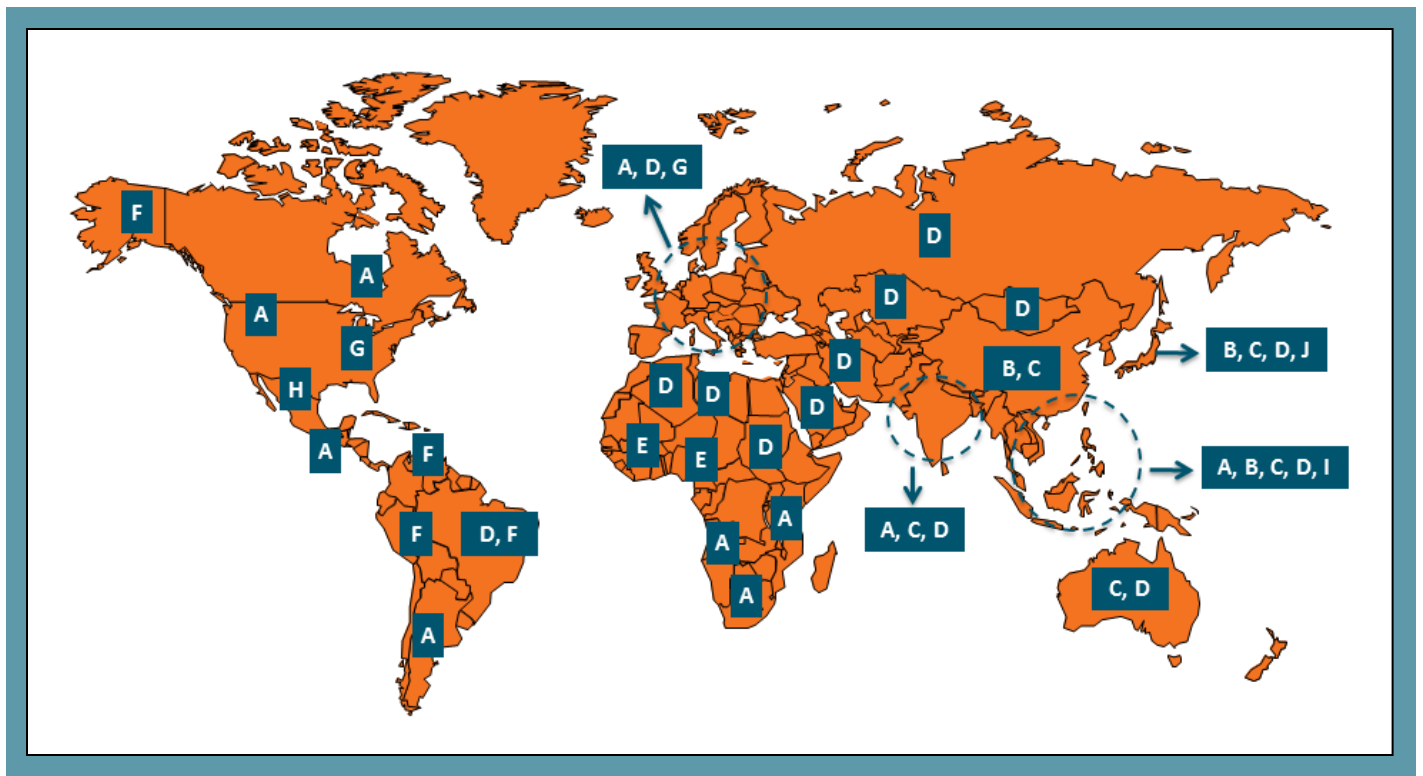
HBV Worldwide AccuSet™ Performance Panel (0805-0247) is a 7-member panel of undiluted, naturally occurring plasma samples. Panel members represent bleeds from multiple individuals positive for HBV of varying genotypes. Each sample represents a single collection event. No preservatives were added.

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 the panel members.

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. All panel members were tested and found negative for anti-HIV-1/2 and anti-HCV.

### Worldwide Distribution of HBV Genotypes



Reference: Zahid Hussain (2013). *Genomic Heterogeneity of Hepatitis Viruses (A-E): Role in Clinical Implications and Treatment, Practical Management of Chronic Viral Hepatitis, Prof. Gaetano Serviddio (Ed.), ISBN: 978-953-51-1109-2, InTech, DOI: 10.5772/55231. Illustration adapted from Figure 6 – Worldwide Geographic Distribution of HBV Genotypes.*

## HBV Genotype and Demographics

Panel Member	SeraCare Batch #	Donor ID #	Country of Origin	Genotype <sup>1</sup>
01	9250960	NA	Romania	A
02	9254960	NA	China	B
03	9233799	BD107125	NA	C
04	9249007	BD110366	NA	D
05	9214340	BD104485	NA	E
06	10034177	BD201352	NA	F
07	9268232	BD200005	NA	H
Test Date				Various
Test Site				Various
Kit Part Code				NA
Kit Lot No.				NA
Kit Exp. Date				NA
Kit Regulatory Status				NA

<sup>1</sup>Members 1, 2, 4, 5, 6, and 7 were genotyped using the Quest Diagnostics HBV Genotype Assay. Member 3 was genotyped using the Institute of Immunology HBV Genotype EIA assay and Quest Diagnostics HBV Genotype Assay.  
NA = Not Available

## HBV DNA

Panel Member	SeraCare Batch #	Siemens VERSANT® HBV bDNA 1.0 Assay (RUO) (IU/mL) <sup>1</sup>	Abbott m2000 Realtime HBV (IU/mL) <sup>1</sup>	Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0 (IU/mL) <sup>1,2</sup>
01	9250960	<b>6283</b>	<b>2685</b>	<b>11124</b>
02	9254960	<b>2053</b>	<b>1815</b>	<b>2003</b>
03	9233799	<b>165043</b>	<b>135748</b>	<b>105569</b>
04	9249007	<b>2714</b>	<b>1348</b>	<b>2306</b>
05	9214340	<b>17857100</b>	<b>58304149</b>	<b>25691526</b>
06	10034177	<b>173633</b>	<b>214364</b>	<b>96582</b>
07	9268232	BLD <sup>3</sup>	<b>110</b>	<b>155</b>
Test Date		06-Jan-15	08-Jan-15	16-Dec-14
Test Site		RL	RL	RL
Kit Part Code		NA	NA	NA
Kit Lot No.		NA	NA	NA
Kit Exp. Date		NA	NA	NA
Kit Regulatory Status		CE IVD	IVD	IVD/CE IVD

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

<sup>2</sup>Results are reported as the mean result of duplicate testing.

<sup>3</sup>Result is <357; below the limit of detection (BLD).

RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

DATA SHEET

## HBsAg and HBeAg

Panel Member	SeraCare Batch #	Abbott PRISM® HBsAg (s/co) <sup>1,2</sup>	DiaSorin ETI-MAK-2 PLUS (HBsAg) (s/co) <sup>1,2</sup>	Ortho Vitros® HBsAg (s/co) <sup>1,3</sup>	DiaSorin ETI-EBK PLUS (HBeAg) (s/co) <sup>1,2</sup>
01	9250960	<b>773.7</b>	<b>68.2*</b>	<b>2865.0</b>	<b>1.19</b>
02	9254960	<b>52.4</b>	<b>55.4</b>	<b>21.7</b>	0.14
03	9233799	<b>876.4</b>	<b>68.2*</b>	<b>3160.0</b>	<b>45.46*</b>
04	9249007	<b>535.2</b>	<b>68.2*</b>	<b>6615.0</b>	0.11
05	9214340	<b>728.5</b>	<b>68.2*</b>	<b>3010.0</b>	0.18
06	10034177	<b>191.1</b>	<b>68.2*</b>	<b>258.0</b>	<b>11.36</b>
07	9268232	<b>689.5</b>	<b>68.2*</b>	<b>4575.0</b>	0.14
Test Date		07-Jan-15	08-Jan-15	10-Jan-15	08-Jan-15
Test Site		RL	SC	RL	SC
Kit Part Code		NA	P001932	NA	P001930
Kit Lot No.		NA	0710450A	NA	0600490A
Kit Exp. Date		NA	21-Feb-15	NA	31-Mar-15
Kit Regulatory Status		IVD/CE IVD	IVD	CE IVD	IVD

<sup>1</sup>Results are reported as a signal to cut-off value (s/co). Signal to cut-off values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

<sup>2</sup>Results are reported as the mean result of duplicate testing.

<sup>3</sup>Results are reported as the mean result of four test results.

\*ALR = Above the limit of reactivity.

SC = SeraCare; RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

## HBV Antibody

Panel Member	SeraCare Batch #	DiaSorin ETI-AB-AUK PLUS (anti-HBs) (s/co) <sup>1,3</sup>	DiaSorin ETI-AB-COREK PLUS (anti-HBc) (co/s) <sup>2,3</sup>	DiaSorin ETI-CORE-IgM K PLUS (anti-HBc IgM) (s/co) <sup>1,3</sup>	DiaSorin ETI-AB-EBK PLUS (anti-HBe) (co/s) <sup>2,3</sup>
01	9250960	0.06	<b>222.00</b>	0.15	0.64
02	9254960	0.21	<b>333.00</b>	<b>1.76</b>	<b>413.14</b>
03	9233799	0.25	<b>333.00</b>	<b>5.69</b>	0.24
04	9249007	0.23	<b>333.00</b>	0.58	<b>413.14</b>
05	9214340	0.24	<b>208.13</b>	<b>2.12</b>	<b>542.25</b>
06	10034177	0.06	0.36	0.11	0.52
07	9268232	0.40	<b>333.00</b>	<b>7.79</b>	<b>723.00</b>
Test Date		08-Jan-15	08-Jan-15	08-Jan-15	09-Jan-15
Test Site		SC	SC	SC	SC
Kit Part Code		P001931	P001927	P001928	P001929
Kit Lot No.		0650360A	9910530AA	0270370A	0490560BA
Kit Exp. Date		31-Mar-15	21-Mar-15	31-Mar-15	31-May-15
Kit Regulatory Status		IVD	IVD	IVD	IVD

<sup>1</sup>Results are reported as a signal to cut-off value (s/co). Signal to cut-off values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

<sup>2</sup>Results are reported as a cut-off to signal value (co/s). Cut-off to signal values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

<sup>3</sup>Results are reported as the mean result of duplicate testing.

\*ALR = Above the limit of reactivity.

SC = SeraCare; IVD = In Vitro Diagnostic

The Package Insert for this panel in PDF form can be found at [www.seracare.com](http://www.seracare.com)

A printed copy of the Package Insert or Data Sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

### ASK ABOUT RELATED SERACARE PRODUCTS

- HBV Disease State Biological Materials
- HBV AccuVer™ Seroconversion Panels

