AccuSet™ HBsAg Performance Panel

0805-0340 / Batch #10326353

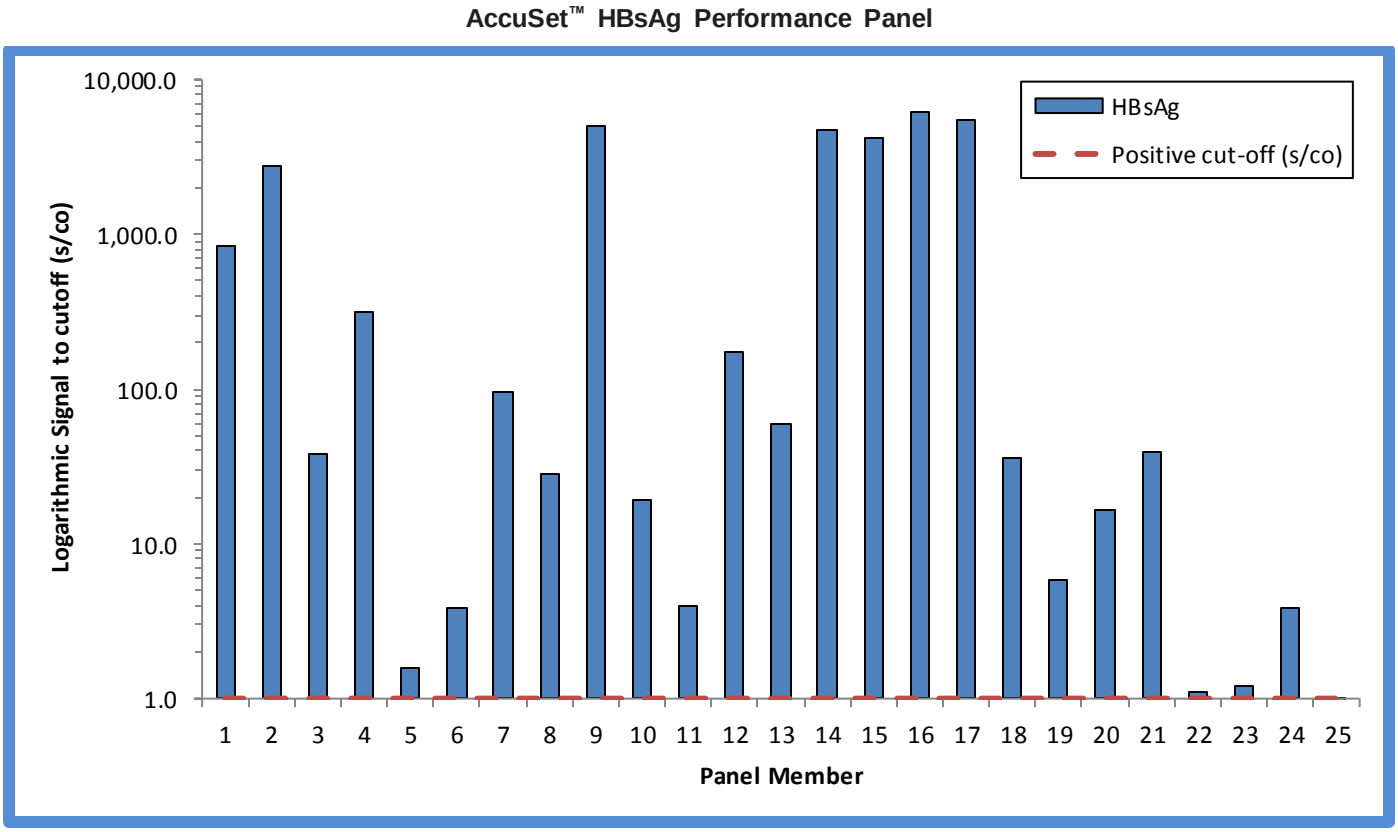
OVERVIEW

AccuSet™ HBsAg Performance Panel (0805-0340) is a 25-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL per vial). Panel members represent bleeds from multiple individuals positive for HBsAg. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HBV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of reactivity for HBsAg test methods. Additional tests performed on HBV DNA, HBeAg, Anti-HBc IgM, Anti-HBc and Anti-HBs are also provided. One sample is included as a non-reactive sample and is negative for all HBV test methods performed.

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.



This graph demonstrates reactivity amongst panel members from the Roche Elecsys 2010 HBsAg test method.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	10266997	BD328494	16-Jul-2016
02	10266998	BD328495	09-Jan-2016
03	9107572	BD110467	NA
04	9107562	BD110465	NA
05	BM204966	BD102166	12-Jan-2006
06	9259534	BD111350	26-Nov-2010
07	10267027	BD328507	26-Dec-2015
08	9120448	BD110515	NA
09	BM206376	BD111334	30-Jun-2006
10	9121493	BD110525	NA
11	BM216724	NA	NA
12	9120182	BD110510	NA
13	9121507	BD110529	NA
14	9253281	BD110945	18-Feb-2011
15	9233766	BD107191	16-Oct-2001
16	10266974	BD328486	20-Mar-2016
17	10267015	BD328502	21-Nov-2015
18	BM217727	BD105187	18-Aug-2007
19	9118028	BD110506	NA
20	9124953	NA	NA
21	BM205270	BD102507	26-Apr-2006
22	9253283	BD110947	14-Jan-2011
23	9242009	BD110034	29-Jun-2009
24	10266961	BD328480	28-Oct-2015
25	10310183	BD349223	31-May-2016

NA = Not Available

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HBV DNA and HBsAg

Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0 (IU/mL)[1,4]	Roche Elecsys® 2010 HBsAg (s/co)[2,4]	Siemens ADVIA Centaur HBsAg (INDEX)[3,4]	Abbott ARCHITECT HBsAg (s/co)[2,4]
01	**>1.7 x 10^8**	**850.0**	**>1000**	**1724.8**
02	**2.9 x 10^5**	**2735.0**	**>1000**	**3751.9**
03	**4.0 x 10^4**	**38.5**	**123.0**	**77.6**
04	**6.1 x 10^4**	**319.1**	**975.6[A]**	**562.7**
05	**8.7 x 10^2**	**1.6**	**3.4**	**2.5**
06	**1.8 x 10^2**	**3.9**	**14.4**	**5.0**
07	<20	**96.0**	**467.0**	**181.6**
08	**1.0 x 10^4**	**28.2**	**97.7**	**55.6**
09	**3.3 x 10^4**	**4995.5**	**>1000**	**4620.8**
10	**2.9 x 10^4**	**19.0**	**43.2**	**35.7**
11	**8.2 x 10^3**	**4.0**	**11.6**	**7.4**
12	**3.1 x 10^4**	**171.9**	**654.2**	**343.1**
13	**3.5 x 10^4**	**59.6**	**226.6**	**118.2**
14	**1.2 x 10^5**	**4775.0**	**>1000**	**4613.0**
15	**8.9 x 10^3**	**4240.5**	**>1000**	**4078.0**
16	**8.4 x 10^4**	**6129.0**	**>1000**	**5159.4**
17	**2.0 x 10^5**	**5551.5**	**>1000**	**5045.3**
18	**2.1 x 10^5**	**35.6**	**154.7**	**101.6**
19	**2.0 x 10^3**	**5.9**	**15.0**	**10.8**
20	**2.2 x 10^4**	**16.6**	**65.6**	**32.2**
21	**3.4 x 10^4**	**38.8**	**215.9**	**121.3**
22	TND	**1.1**	**1.5**	**1.9**
23	**5.5 x 10^2**	**1.2**	**2.6**	**1.4**
24	TND	**3.9**	**11.2**	**6.7**
25	TND	0.4	<0.1	0.1
Test Date	22-Mar-2018	06-Apr-2018	16-Mar-2018	15-Mar-2018
Test Site	RL	RL	RL	SC
Kit Part Code	NA	NA	NA	4P53
Kit Lot No.	NA	NA	NA	81112FN00
Kit Exp. Date	NA	NA	NA	06-Jun-2018
Kit Regulatory Status	IVD/CE	IVD	IVD/CE	IVD/CE

[1]Results are reported as international units per milliliter (IU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as signal-to-cutoff ratio (s/co); positive/reactive results are noted in bold red.
[3]Results are reported as index; positive/reactive results are noted in bold red.
[4]Results are reported as the mean result of duplicate testing.
[A]Member tested off-scale at >1000 for one run and 975.6 on second run.
TND = Target Not Detected
RL = Reference Lab; SC = SeraCare; NA = Not Available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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HBsAg

Panel Member	Ortho VITROS HBsAg (s/co)[1,3]	Bio-Rad Genetic Systems™ HBsAg EIA 3.0 (s/co)[1,3]	DiaSorin Liaison XL HBsAg (IU/mL)[2,3]	Abbott PRISM HBsAg Confirmatory[3]
01	**883.5**	**>34.2**	**>150.0**	**POS**
02	**2405.0**	**>34.2**	**>150.0**	**POS**
03	**45.4**	**25.6**	**1.8**	**POS**
04	**312.0**	**>34.2**	**14.5**	**POS**
05	**1.0**	**1.6**	0.0	**POS**
06	**7.1**	**3.8**	**0.1**	**POS**
07	**67.3**	**18.5**	**1.6**	**POS**
08	**29.3**	**26.0**	**1.4**	**POS**
09	**3680.0**	**>34.2**	**>150.0**	**POS**
10	**17.5**	**8.4**	**0.7**	**POS**
11	**2.9**	**4.7**	**0.2**	**POS**
12	**212.0**	**>34.2**	**5.0**	**POS**
13	**50.6**	**28.3**	**3.5**	**POS**
14	**3945.0**	**>34.2**	**>150.0**	**POS**
15	**3150.0**	**>34.2**	**>150.0**	**POS**
16	**4980.0**	**>34.2**	**>150.0**	**POS**
17	**4670.0**	**>34.2**	**>150.0**	**POS**
18	**81.6**	**32.7**	**1.5**	**POS**
19	**4.7**	**5.7**	**0.2**	**POS**
20	**78.3**	**19.3**	**0.5**	**POS**
21	**64.0**	**31.6**	**1.7**	**POS**
22	0.2	0.7	0.0	**POS**
23	0.7	**1.1**	0.0	**POS**
24	**3.7**	**4.0**	**0.1**	**POS**
25	0.1	0.2	0.0	NEG
Test Date	19-Mar-2018	15-Mar-2018	25-Mar-2018	05-Apr-2018
Test Site	RL	SC	RL	RL
Kit Part Code	NA	32591	NA	6D16-48
Kit Lot No.	NA	160MCC-05	NA	82269LI00
Kit Exp. Date	NA	30-Nov-2018	NA	18-Oct-2018
Kit Regulatory Status	IVD/CE	IVD	CE	IVD

[1]Results are reported as signal-to-cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as international units per milliliter (IU/mL); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
POS = Positive; NEG = Negative
RL = Reference Lab; SC = SeraCare; NA = Not Available
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HBeAg and Anti-HBe

Panel Member	Abbott ARCHITECT HBeAg (s/co)[1,3]	DiaSorin ETI-EBK Plus HBeAg EIA (s/co)[1,3]	DiaSorin ETI-AB-EBK Plus Anti-HBe EIA (co/s)[2,3]
01	**312.9**	**>62.5**	0.2
02	**111.2**	**>62.5**	0.2
03	0.6	**1.6**	0.5
04	**1.8**	**19.1**	0.4
05	0.3	0.1	0.5
06	0.3	0.1	0.6
07	0.3	0.0	**187.5**
08	0.4	0.5	0.5
09	0.6	**2.4**	**1.0**
10	0.5	**1.4**	0.6
11	0.3	0.2	0.5
12	0.6	**4.6**	0.5
13	0.5	**1.7**	0.5
14	0.4	**3.1**	0.9
15	0.5	**2.1**	**1.4**
16	**1.2**	**2.4**	0.9
17	**1.1**	**2.0**	**1.5**
18	**3.6**	**27.3**	0.4
19	0.3	0.1	0.5
20	0.4	**1.3**	0.5
21	**1.0**	**3.2**	0.6
22	0.3	0.0	0.6
23	0.3	0.0	0.6
24	0.3	0.1	**7.2**
25	0.3	0.0	0.6
Test Date	25-Mar-2018	03-Apr-2018	29-Mar-2018
Test Site	RL	SC	SC
Kit Part Code	NA	P001930	P001929
Kit Lot No.	83044LI00	0600630AA	0490710A
Kit Exp. Date	13-Oct-2018	30-Sep-2018	27-Sep-2018
Kit Regulatory Status	IVD/CE	IVD	IVD

[1]Results are reported as signal-to-cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as cutoff-to-signal ratio (c/so); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
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Anti-HBc IgM, Anti-HBc and Anti-HBs

Panel Member	DiaSorin ETI-CORE-IgMK PLUS Anti-HBc IgM EIA (s/co)[1,3]	DiaSorin ETI-AB-COREK PLUS Anti-HBc EIA (co/s)[2,3]	DiaSorin ETI-AB-AUK Plus Anti-HBs EIA (s/co)[1,3]
01	**8.9**	**8.1**	0.1
02	0.3	**>177.0**	0.1
03	0.1	0.2[4]	0.1
04	0.1	0.1	0.1
05	0.1	0.2	0.0
06	0.1	0.3	0.0
07	0.1	**>177.0**	0.1
08	0.1	0.3	0.0
09	0.3	**>177.0**	0.0
10	0.1	0.2	0.0
11	0.1	0.2	0.0[4]
12	0.1	0.1	0.1
13	0.1	0.2	0.1
14	0.8	**>177.0**	0.1
15	0.8	**>177.0**	0.1
16	0.3	**88.5**	0.0[4]
17	**1.7**	**>177.0**	0.1
18	0.1	0.2	0.0
19	0.1	0.2	0.0
20	0.1	0.2[4]	0.1
21	0.9	**14.8**	0.0
22	0.1	0.2	0.0
23	0.1	0.3	0.0
24	0.1	**>177.0**	0.1
25	0.1	0.2	0.1
Test Date	20-Mar-2018	27-Mar-2018, 28-Mar-2018[4]	21-Mar-2018, 22-Mar-2018[4]
Test Site	SC	SC	SC
Kit Part Code	P001928	P001927	P001931
Kit Lot No.	0270450A	9910650A	0650440A
Kit Exp. Date	30-Jun-2018	28-Mar-2018	30-Jun-2018
Kit Regulatory Status	IVD	IVD	IVD

[1]Results are reported as signal-to-cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as cutoff-to-signal ratio (c/so); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
[4]Members tested in a separate run from other members in the panel.
SC = SeraCare
IVD = In Vitro Diagnostic

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.