

Hepatitis B Surface Antigen (HBsAg) AccuSpan™

Sensitivity Panel

2410-0161

OVERVIEW

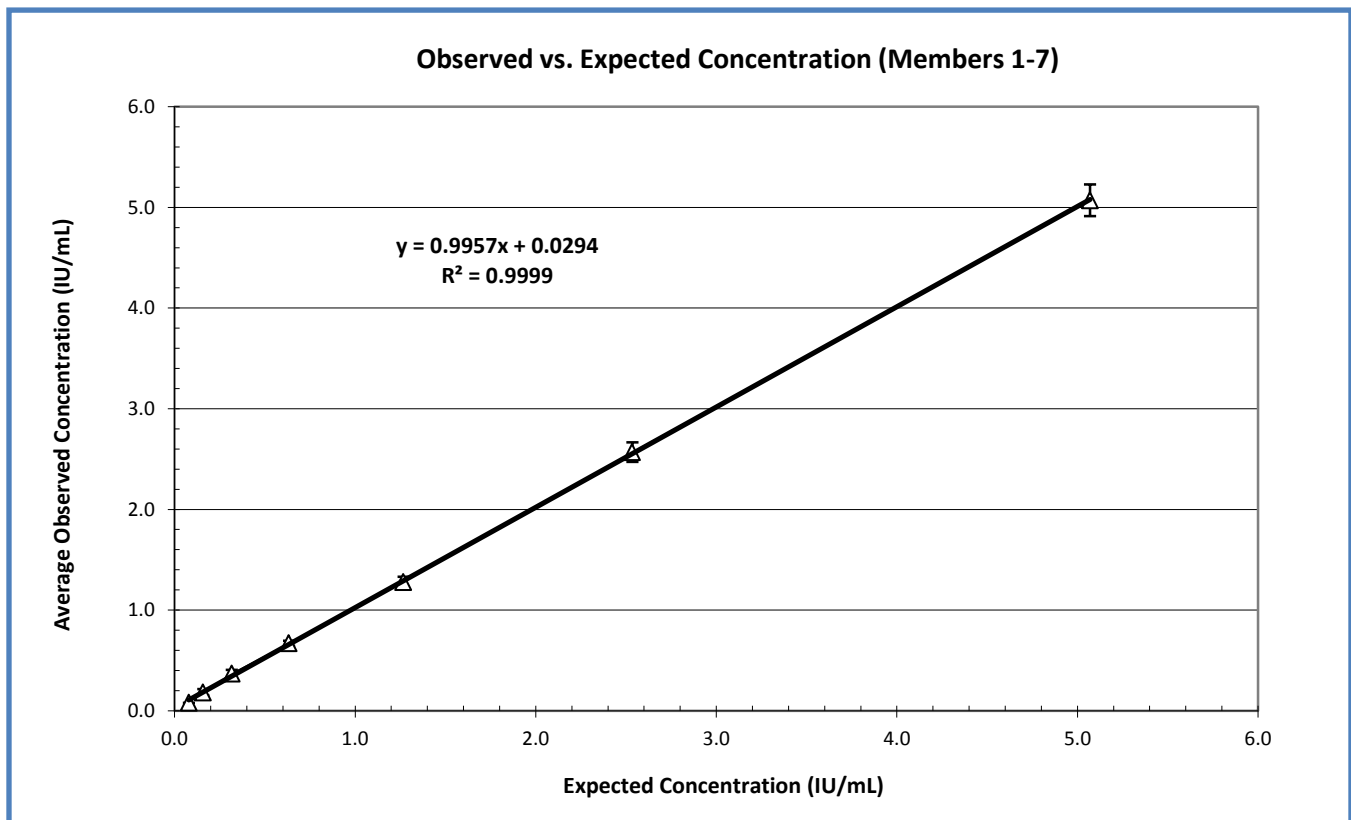
The HBsAg AccuSpan™ Sensitivity Panel (2410-0161) is a 15-member panel composed of two sets of dilution series of HBsAg subtypes ad and ay. Each dilution series consists of seven members representing serial two-fold dilutions of positive serum, with established reactivity for each HBsAg subtype, diluted in negative diluent. The panel also includes a negative member prepared from the negative diluent. The diluent was prepared from pooled normal human serum non-reactive for HBsAg that was filtered through a 0.2 micron filter. Each member contains a preservative (0.1% ProClin 300).

Results are reported for each panel member on each specific test method. Linearity for each dilution series is shown graphically by plotting observed results against expected results. The WHO Reference Panel was tested in the same run as the HBsAg AccuSpan Sensitivity Panel members. Both expected and observed results for the standards are reported; expected results for the WHO panel members are the WHO assigned values.

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: These materials have not been treated and should be considered biohazardous. Follow Universal Precautions.

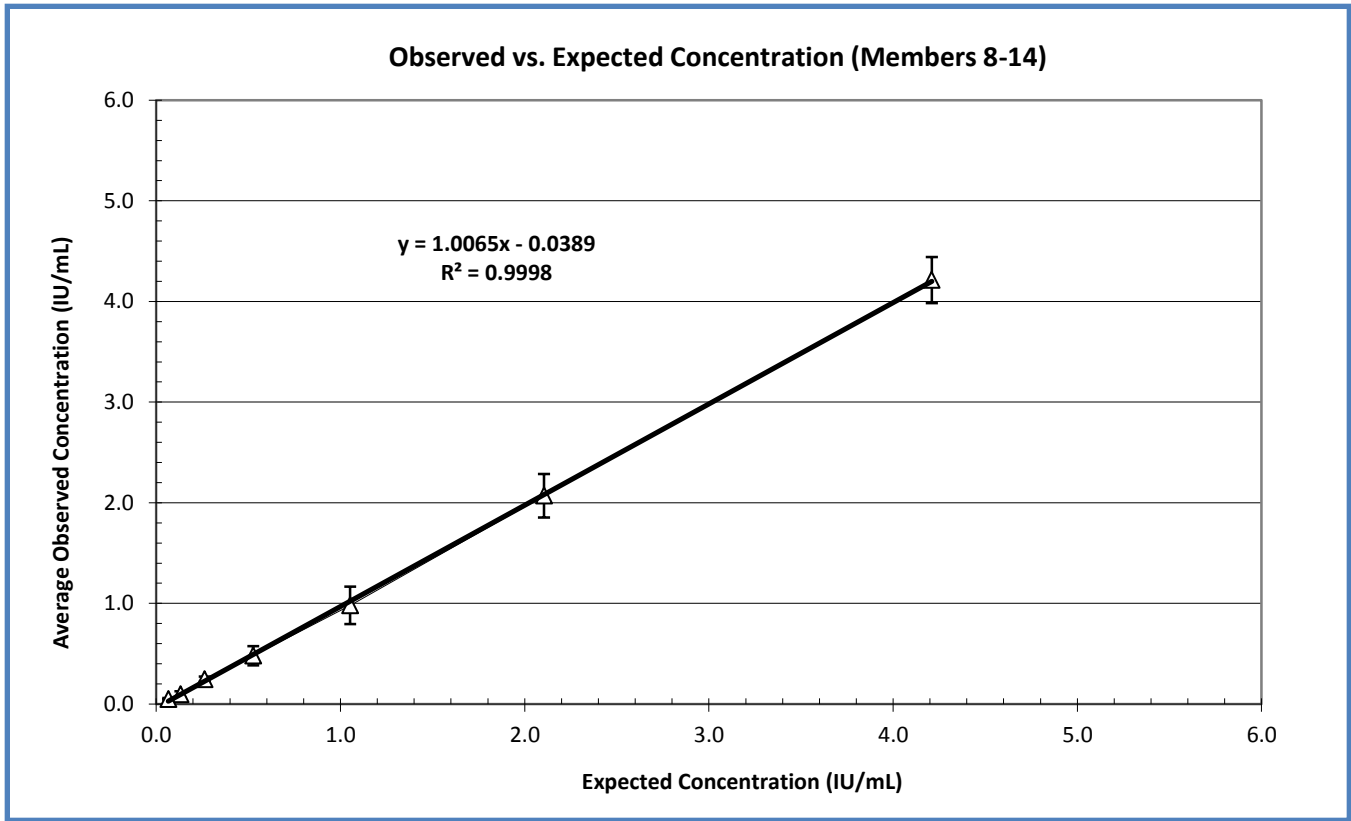
HBsAg AccuSpan Sensitivity Panel Members 1-7



HBsAg results were obtained using the Abbott ARCHITECT quantitative HBsAg test method. A line of best fit is shown.

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HBsAg AccuSpan Sensitivity Panel Members 8-14



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HBsAg AccuSpan Sensitivity Panel

Panel Member	HBsAg Subtype	Abbott ARCHITECT Quantitative HBsAg (IU/mL) ¹	Abbott ARCHITECT Qualitative HBsAg (S/CO) ¹
01	ad	5.07	238.4
02	ad	2.57	120.1
03	ad	1.28	61.8
04	ad	0.67	30.8
05	ad	0.37	15.4
06	ad	0.18	7.8
07	ad	0.08	4.0
08	ay	4.21	204.9
09	ay	2.07	102.4
10	ay	0.98	52.7
11	ay	0.48	25.6
12	ay	0.25	13.3
13	ay	0.10	6.4
14	ay	0.05	3.4
15	n/a	0.00	0.2
<hr/>			
Test Date		20-Nov-15	20-Nov-15
Test Site		RL	SeraCare
Test Kit Cutoff		0.05	1.00
Test Kit Conversion Factor		n/a	n/a
Test Kit Part Code		n/a	4P53
Test Kit Lot No.		57375LH00	52424LF00
Test Kit Regulatory Status		IVD/CE	IVD/CE

¹Results are reported as the mean result of triplicate testing. Results in red are considered positive.
 RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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WHO HBsAg subtype adw2, genotype A Reference Panel (NIBSC code: 03/262)

Sample ID	Expected Concentration (IU/mL) ²	Observed Concentration (IU/mL) ^{1,2}	Standard Deviation	% Difference ³
Sample A	8.25	10.59	0.19	28%
Sample B	2.06	2.75	0.12	34%
Sample C	0.52	0.68	0.02	30%
Sample D	0.13	0.17	0.01	33%
Sample E	0.00	0.00	0.00	n/a

Test Date	19-Nov-15
Test Site	RL
Test Kit Cutoff	0.05
Test Kit Conversion Factor	n/a
Kit Part Code	n/a
Kit Lot No.	57375LH00
Kit Regulatory Status	IVD/CE

¹Results are reported as the mean result of triplicate testing. Results in red are considered positive.

²WHO panel was tested in the same test run as the HBsAg AccuSpan™ Sensitivity Panel members.

³Percentage difference is how much the observed concentration differs from the expected concentration. Values calculated for reference only. Some laboratories may use the data to apply a correction factor to the test results.

RL = Reference Lab; 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

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