HBV DNA AccuSpan™ Linearity Panel

2410-0162 / Batch # 10187874

OVERVIEW

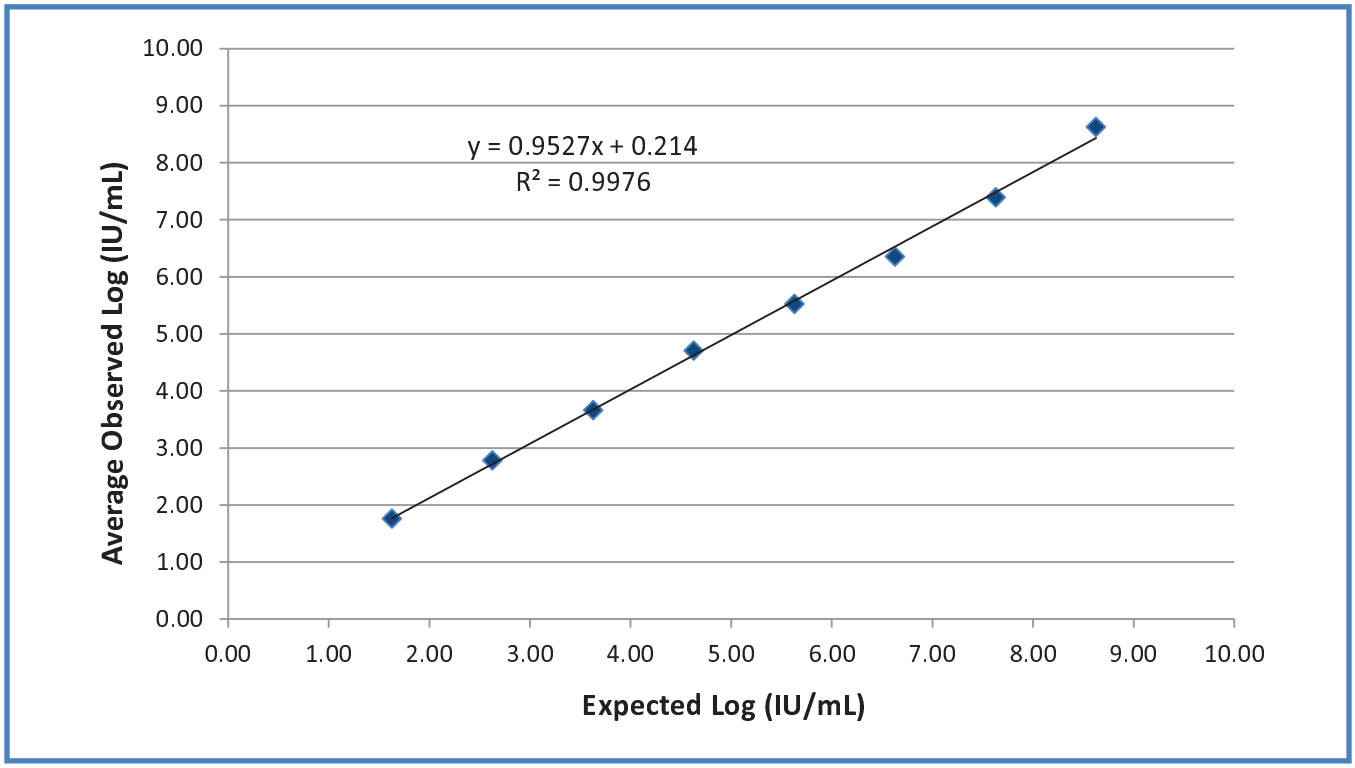
The HBV DNA AccuSpan™ Linearity Panel is a nine member panel made from serial dilutions of plasma with established reactivity for Hepatitis B (HBV) DNA. This panel consists of eight members representing serial log dilutions of HBV DNA positive plasma in HBV DNA negative diluent, one negative member prepared from the diluent, and one member of diluent to perform additional dilutions as desired. The diluent was prepared from normal human plasma that was filtered through a 0.2 µm filter. Sodium azide (0.09%) was added as a preservative.

Results are reported for each panel member on each specific test method. Linearity is shown graphically by plotting observed results against expected results. The 3rd WHO International Standard for Hepatitis B virus (NIBSC code: 10/264) was tested in the same run as the HBV DNA AccuSpan Linearity Panel members. Both expected and observed results for the standards are reported; expected results for the WHO standards 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.

HBV DNA AccuSpan Linearity Panel Members 1-8



HBV DNA results were obtained using the Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Test Version 2.0 test method. Results are the mean of three replicates. A line of best fit is shown.

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HBV DNA AccuSpan Linearity Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Version 2.0[1] log IU/mL	Abbott *m*2000 RealTime HBV DNA[1] log IU/mL
01	**8.63**[2]	**8.72**
02	**7.39**	**7.55**
03	**6.35**	**6.57**
04	**5.52**	**5.48**
05	**4.70**	**4.49**
06	**3.66**	**3.45**
07	**2.78**	**2.69**
08	**1.76**	**1.95**
09	TND	TND
Test Date	1-May-2016	3-May-2016
Test Site	RL	RL
Test Kit Range	20 to 170,000,000 IU/mL	15 to 1,000,000,000 IU/mL
Test Kit Conversion Factor	1 IU = 5.82 copies	1 IU = 3.41 copies
Test Kit Part Code	NA	NA
Test Kit Lot No.	W11250	10159741
Kit Exp. Date	31-July-2017	28-Mar-2017
Test Kit Regulatory Status	IVD	IVD

[1]Results are reported as the mean result of three replicates. Log IU/mL is shown. Results in bold red are considered positive.
[2]Panel member was tested at a 1:10 dilution and results were corrected for the dilution factor.
TND = Target Not Detected
RL = Reference Lab; IVD = In Vitro Diagnostic; NA = Not available

DATA SHEET

HBV DNA AccuSpan™ Linearity Panel

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3rd WHO International Standard HBV International Standard (NIBSC code: 10/264)

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Version 2.0 (log IU/mL)[1]	% Difference[2]
Sample A1	5.00	**5.13**	2.55
Sample A2	4.70	**4.81**	2.29
Sample A3	4.00	**4.21**	5.27
Sample A4	3.70	**3.97**	7.37
Sample A5	3.00	**3.31**	10.49
Test Date		1-May-2016	
Test Site		RL	
Test Kit Range		20 to 170,000,000 IU/mL	
Test Kit Conversion Factor		1 IU =5.82 copies	
Kit Part Code		NA	
Kit Lot No.		W11250	
Kit Exp. Date		31-July-2017	
Kit Regulatory Status		IVD	

[1]WHO panel was tested in the same test run as the HBV DNA AccuSpan™ Linearity Panel members. Samples were run in singlet. Results in bold red are considered positive.

[2]Percent 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; NA = Not available

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