AccuSpan™ HBV DNA Linearity Panel

PHD802 (2410-0162) / Batch # 10439611

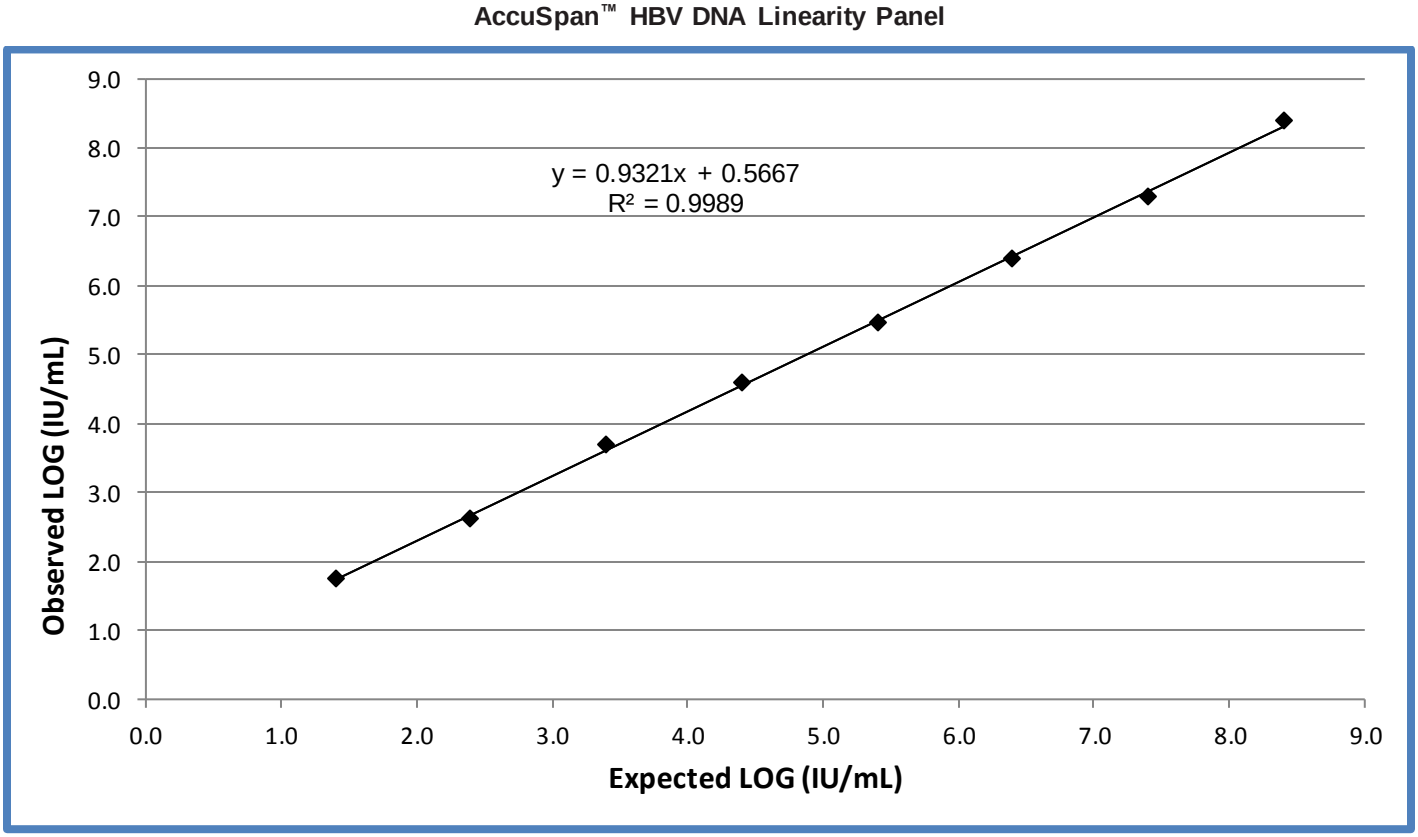
OVERVIEW

AccuSpan™ HBV DNA Linearity Panel PHD802 (2410-0162 / Batch #10439611) 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, and one negative member prepared from the diluent. 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. A series of dilutions from the 3rd WHO International Standard for Hepatitis B virus (NIBSC code: 10/264) was tested in the same run as the AccuSpan HBV DNA Linearity Panel members. Both expected and observed results for the standards are reported; the expected values from the WHO standards are the dilution estimated 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 results were obtained using the Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Version 2.0 test method. Member #1 is the mean result of triplicate testing from a dilution of 1:100. Member #2 - #8 is the mean of three replicates. A line of best fit is shown.

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HBV DNA

Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Version 2.0 (log IU/mL)[1,2]	Abbott *m*2000 RealTi*m*e HBV DNA (log IU/mL)[1,2]
01	**8.40**[3]	**8.49**
02	**7.28**	**7.23**
03	**6.40**	**6.36**
04	**5.46**	**5.33**
05	**4.60**	**4.32**
06	**3.68**	**3.39**
07	**2.62**	**2.48**
08	**1.74**	**1.75**
09	TND	TND
Test Date	22-Aug-2019 05-Sep-2019[3]	26-Aug-2019
Test Site	RL	RL
Test Kit Range	20 to 170,000,000 IU/mL 5.82 copies = 1 IU	15 to 1,000,000,000 IU/mL 3.41 copies = 1 IU
Test Kit Part Code	NA	NA
Test Kit Lot No.	F06482	491138
Test Kit Exp. Date	31-Oct-2020	05-Mar-2020

[1]Results are reported as log International Units per mL (log IU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as the mean result of triplicate testing.
[3]Results are reported as the mean result of triplicate testing from a dilution of 1:100 tested on 05-Sep-2019.
RL = Reference Lab; NA = Not available

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3rd WHO International HBV DNA Standard (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 1	**5.00**	**5.10**	**2.0**
Sample 2	**4.70**	**4.86**	**3.5**
Sample 3	**4.00**	**4.28**	**7.0**
Sample 4	**3.70**	**3.98**	**7.5**
Sample 5	**3.00**	**3.16**	**5.5**
Test Date		22-Aug-2019	
Test Site		RL	
Test Kit Range		15 to 100,000,000 IU/mL 5.82 copies = 1 IU	
Test Kit Part Code		NA	
Test Kit Lot No.		F06482	
Test Kit Exp. Date		31-Oct-2020	

[1]WHO panel was tested in the same test run as the AccuSpan™ HBV DNA Linearity Panel members. Samples were run in singlicate. Positive/reactive results are noted in bold red.
[2]Percentage difference is how much the observed concentration differs from the expected concentration. Values calculated for reference only. Laboratories may use the data to apply a correction factor to the test results.
RL = Reference Lab; 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.