AccuSpan™ HBV DNA Linearity Panel

2410-0162 / Batch #10623171

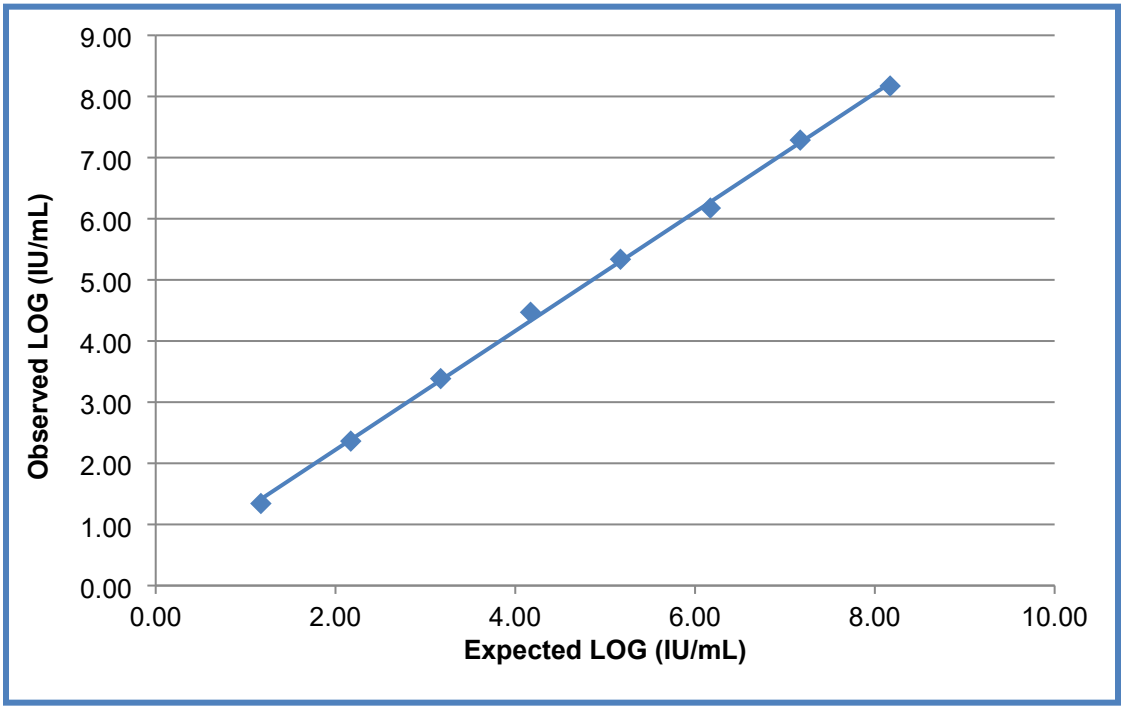
OVERVIEW

AccuSpan™ HBV DNA Linearity Panel (2410-0162 / Batch #10623171) 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. The WHO International Standard 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 standard are based upon application of a dilution factor to the WHO assigned value.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes.
LGC 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 Test v2.0 test method. Results are 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 Test v2.0 (log IU/mL)[1,2]	Abbott m2000 RealTi*me* HBV Assay (log IU/mL)[1,2]
01	**8.17**[3]	**8.11**[3]
02	**7.29**	**7.12**
03	**6.17**	**6.13**
04	**5.34**	**5.16**
05	**4.47**	**4.12**
06	**3.39**	**3.16**
07	**2.36**	**2.27**
08	**1.34,** <1.30, <1.30*	**1.23**
09	TND	TND
Test Date	24-Jun-2022	9-Jun-2022
Test Site	RL	RL
Test Kit Range	20 to 170,000,000 IU/mL 1.30 to 8.23 log IU/mL	10 to 1,000,000,000 IU/mL 1.00 to 9.00 log IU/mL
Kit Part Code	NA	NA
Kit Lot No.	H26221	10002677
Kit Exp. Date	30-Apr-2023	31-Jul-2022

[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]Panel member #1 was tested at a 1:100 dilution and results were corrected for the dilution factor.
*Interpretation variability based on triplicate testing, individual replicates reported.
TND = Target Not Detected; RL = Reference Lab; NA = Not Available

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4th WHO HBV DNA International Standard (10/266)

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Test v2.0 (log IU/mL)[1]	% Difference[2]
Sample 01	5.00	**5.08**	1.6
Sample 02	4.70	**4.83**	2.7
Sample 03	4.00	**4.17**	4.4
Sample 04	3.70	**3.77**	1.8
Sample 05	3.00	**3.17**	5.6
Test Date		24-Jun-2022	
Test Site		RL	
Test Kit Range		20 to 170,000,000 IU/mL 1.30 to 8.23 log IU/mL	
Kit Part Code		NA	
Kit Lot No.		H26221	
Kit Exp. Date		30-Apr-2023	

[1]WHO panel was tested in the same test run as the AccuSpan™ HBV DNA Linearity Panel members. Samples were run in singlet. 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 CDx-Info@LGCGroup.com or by phone at 508.244.6400.