

AccuSpan[™] HBV DNA Linearity Panel

2410-0162 / Batch #10718639

OVERVIEW

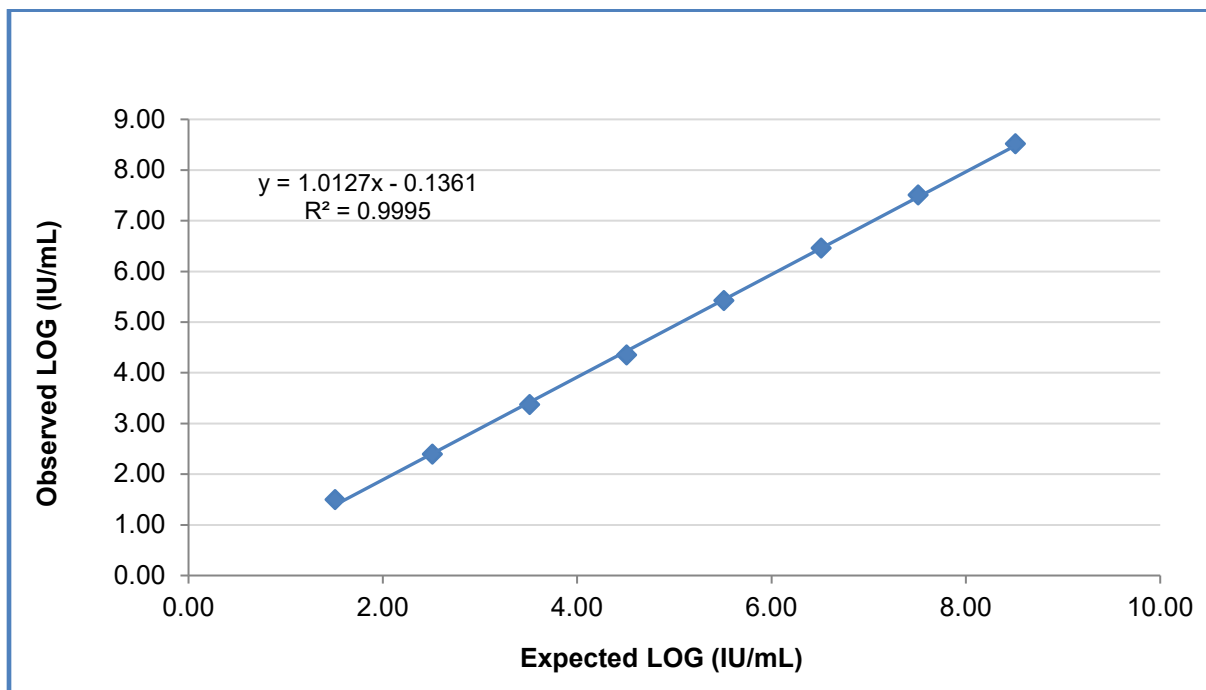
AccuSpan[™] HBV DNA Linearity Panel 2410-0162 / Batch #10718639 is a nine-member panel made from serial dilutions of plasma with established reactivity for Hepatitis B (HBV) DNA. This panel consists of eight members representing serial log dilutions of HBV DNA positive plasma in HBV DNA negative diluent, 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.

AccuSpan[™] HBV DNA Linearity Panel



HBV DNA results were obtained using Roche cobas® 6800/8800 HBV test method. Results are the mean of three replicates. A line of best fit is shown.

AccuSpan™ HBV DNA Linearity Panel

2410-0162 / Batch #10718639

HBV DNA¹

Panel Member	Roche cobas® 6800/8800 HBV Test (IU/mL)	Roche cobas® 6800/8800 HBV Test (log IU/mL)
01	3.28 x 10⁸*	8.51
02	3.24 x 10⁷	7.50
03	2.89 x 10⁶	6.46
04	2.64 x 10⁵	5.42
05	2.24 x 10⁴	4.35
06	2.36 x 10³	3.37
07	2.46 x 10²	2.39
08	3.13 x 10¹	1.49
09	TND	TND
Test Date	19-Jul-2024, 22-Aug-2024	
Test Site	RL	
Test Kit Range	10 – 1.00 x 10 ⁹ IU/mL 1.00 – 9.00 log IU/mL	
Kit Part Code	N/A	
Kit Lot No.	N/A	
Kit Exp. Date	N/A	

¹Results are reported as the mean result of triplicate testing; positive/reactive results are noted in bold red.

*Panel Member #1 was tested at a 1:100 dilution and results were corrected for the dilution factor.

TND = Target Not Detected; RL = Reference Lab; NA = Not Available

AccuSpan™ HBV DNA Linearity Panel

2410-0162 / Batch #10718639

HBV DNA¹

Panel Member	Abbott Alinity m HBV Assay (IU/mL)	Abbott Alinity m HBV Assay (log IU/mL)
01	3.02 x 10⁸*	8.48
02	2.13 x 10⁷	7.33
03	2.13 x 10⁶	6.33
04	2.64 x 10⁵	5.41
05	3.53 x 10⁴	4.53
06	2.66 x 10³	3.39
07	4.81 x 10²	2.67
08	8.00 x 10¹	1.90
09	TND	TND
Test Date	15-Jul-2024, 23-Aug-2024	
Test Site	RL	
Test Kit Range	10 – 1.00 x 10 ⁹ IU/mL 1.00 – 9.00 log IU/mL	
Kit Part Code	N/A	
Kit Lot No.	389540	
Kit Exp. Date	10-Apr-2025	

¹Results are reported as the mean result of triplicate testing; positive/reactive results are noted in bold red.

*Panel Member #1 was tested at a 1:100 dilution and results were corrected for the dilution factor.

TND = Target Not Detected; RL = Reference Lab; NA = Not Available

AccuSpan™ HBV DNA Linearity Panel

2410-0162 / Batch #10718639

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

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche cobas® 6800/8800 HBV Test (log IU/mL) ¹	% Difference ²
Sample 01	5.00	5.11	2.1
Sample 02	4.70	4.72	0.3
Sample 03	4.00	4.03	0.8
Sample 04	3.70	3.78	2.1
Sample 05	3.00	3.00	0.0
Test Date		19-Jul-2024	
Test Site		RL	
Test Kit Range		10 – 1.00 x 10 ⁹ IU/mL 1.00 – 9.00 log IU/mL	
Kit Part Code		N/A	
Kit Lot No.		N/A	
Kit Exp. Date		N/A	

¹WHO 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.

²Percentage difference is how much the observed log concentration differs from the expected log 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.