AccuSpan™ BKV Linearity Panel

2410-0344 / Batch #10799525

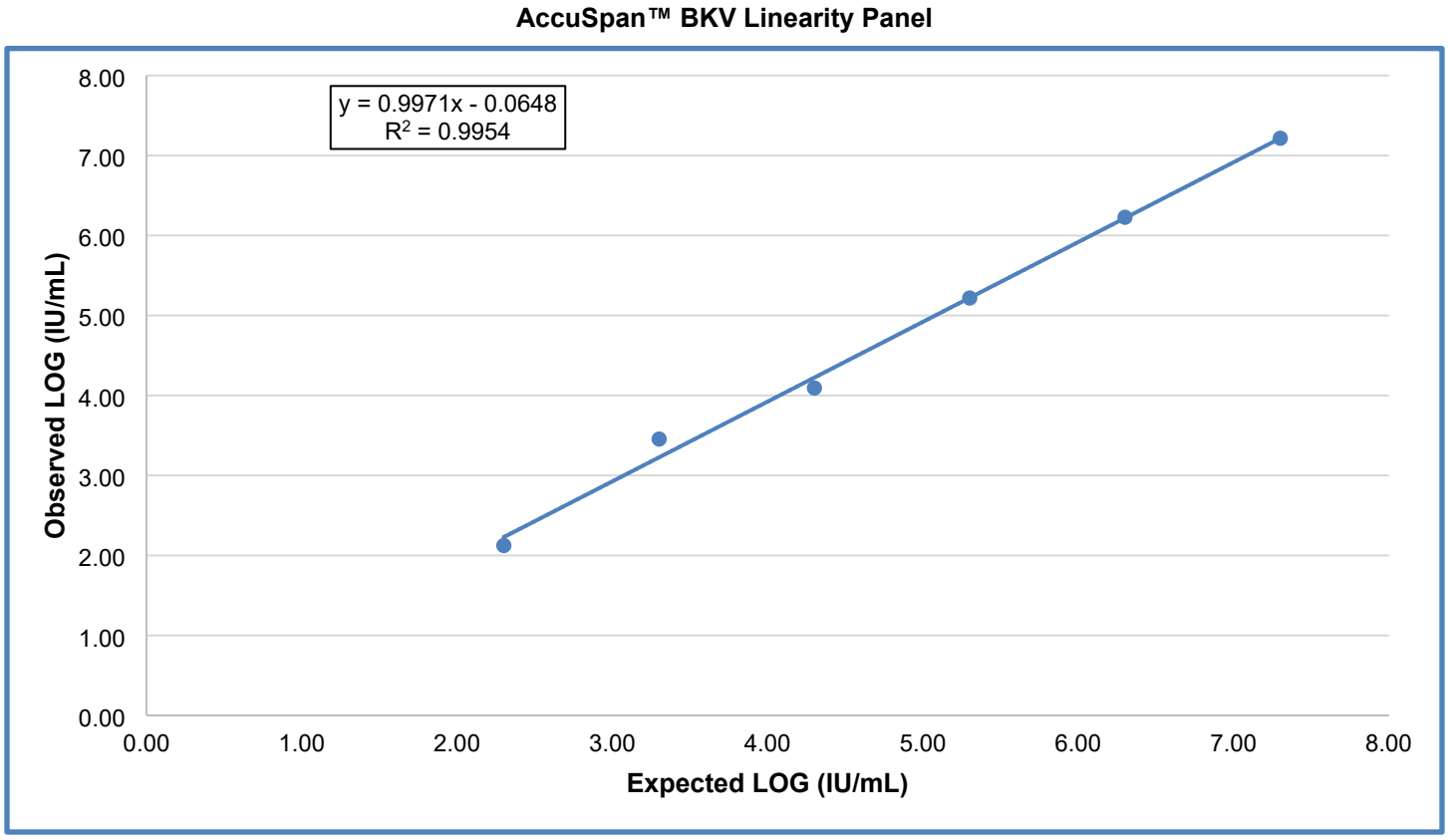
OVERVIEW

The AccuSpan™ BKV Linearity Panel 2410-0344 / Batch #10799525 is a seven-member panel consisting of six members representing serial log dilutions of cultured BK virus, with established reactivity for BKV DNA, in BKV DNA negative diluent. This panel also consists of one negative member prepared from the diluent. The diluent was prepared from normal human plasma that was 0.2 micron filtered. Sodium azide (0.09%) was added as a preservative.

Roche cobas® 6800/8800 BKV Assay results are reported for each panel member. Linearity is shown graphically by plotting observed results against expected results. The WHO International Standard was tested in the same run as the AccuSpan™ BKV 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.



BKV DNA results were obtained using the Roche cobas® 6800/8800 BKV test method. A line of best fit is shown.

AccuSpan™ BKV Linearity Panel

2410-0344 / Batch #10799525

BKV DNA

Panel Member	Roche cobas® 6800/8800 BKV Test[1] log (IU/mL)
01*	**7.22**
02	**6.23**
03	**5.22**
04	**4.09**
05	**3.46**
06	**2.12**
07	TND
Test Date	NA
Test Site	RL
Test Kit Range	21.5 – 100,000,000 IU/mL 1.33 – 8.00 log IU/mL
Kit Part Code	NA
Kit Lot No.	NA
Kit Exp. Date	NA

[1]Results are reported as the mean result of three replicates; positive/reactive results are noted in bold red.
*Panel member #1 was tested at a 1:10 dilution and results were corrected for the dilution factor.
TND = Target Not Detected; RL = Reference Lab; NA = Not Available

AccuSpan™ BKV Linearity Panel

2410-0344 / Batch #10799525

WHO International Standard: 1ST BKV International Standard (NIBSC Code: 14/212)

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche cobas® 6800/8800 BKV Test (log IU/mL)[1]	% Difference[2]
01	6.18	**6.22**	0.59%
02	5.18	**5.23**	0.90%
03	4.18	**4.26**	1.82%
Test Date		NA	
Test Site		RL	
Test Kit Range		21.5 – 100,000,000 IU/mL 1.33 – 8.00 log IU/mL	
Kit Part Code		NA	
Kit Lot No.		NA	
Kit Exp. Date		NA	

[1]WHO panel was tested in the same test run as the AccuSpan™ BKV Linearity Panel members. Samples were run in triplicate. Positive/reactive results are noted in bold red.

[2]Percentage 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.