

AccuSpan™ CMV DNA Linearity Panel

2410-0174 / Batch #10817494

OVERVIEW

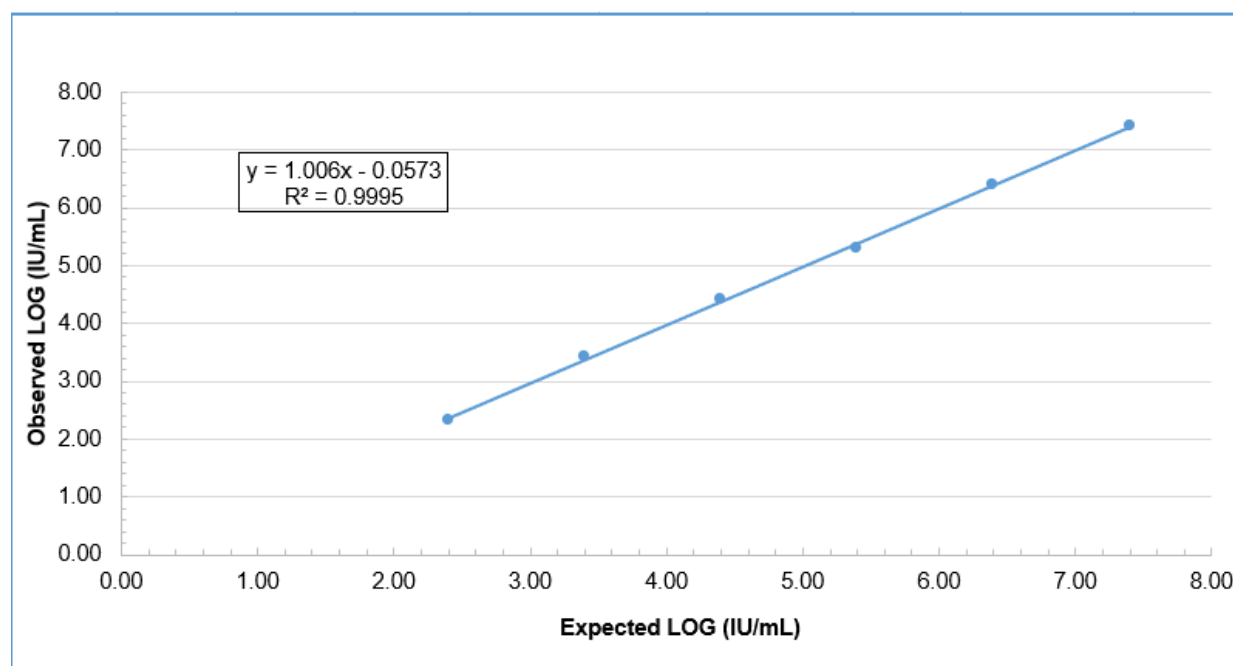
The AccuSpan™ CMV DNA Linearity Panel 2410-0174 / Batch #10817494 is a nine-member panel consisting of seven members representing serial log dilutions of cultured CMV virus, with established reactivity for CMV (Cytomegalovirus) DNA, in CMV DNA negative diluent. This panel also consists of one negative 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 0.2 micron filtered. Sodium azide (0.09%) was added as a preservative.

Roche cobas® 6800/8800 CMV 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™ CMV 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 Clinical Diagnostics 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™ CMV DNA Linearity Panel



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

AccuSpan™ CMV DNA

Linearity Panel

2410-0174 / Batch #10817494

CMV DNA

Roche cobas® 6800/8800 CMV Test ¹	
Panel Member	log (IU/mL)
01 ²	7.40
02	6.39
03	5.30
04	4.40
05	3.41
06	2.33
07	TND, 1.97, <1.54, <1.54, <1.54*
08	TND
09	TND
Test Date	NA
Test Site	RL
Test Kit Range	34.5 to 1.00E+07 IU/mL 1.54 to 7.00 log IU/mL
Kit Part Code	NA
Kit Lot No.	NA
Kit Exp. Date	NA

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

²Panel Member #1 was tested at a 1:10 dilution and results were corrected for the dilution factor.

*Interpretation variability; individual replicates reported.

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

AccuSpan™ CMV DNA Linearity Panel

2410-0174 / Batch #10817494

WHO International Standard: 1st CMV DNA International Standard (NIBSC Code: 09/162)

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche cobas® 6800/8800	
		CMV Test (log IU/mL) ¹	% Difference ²
01	5.70	5.70	0.0
02	5.00	5.05	0.9
03	4.70	4.63	-1.5
04	4.00	4.00	0.0
05	3.70	3.77	1.8
Test Date		NA	
Test Site		RL	
Test Kit Range		34.5 to 1.00E+07 IU/mL 1.54 to 7.00 log IU/mL	
Kit Part Code		NA	
Kit Lot No.		NA	
Kit Exp. Date		NA	

¹WHO panel was tested in the same test run as the AccuSpan™ CMV DNA Linearity Panel members. Samples were run in singlicate. Positive/reactive results are noted in bold red.

²Percentage 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.