AccuSpan™ CMV DNA Linearity Panel

2410-0174 / Batch #10633101

OVERVIEW

The AccuSpan™ CMV DNA Linearity Panel 2410-0174 / Batch #10633101 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® AmpliPrep/COBAS® TaqMan® 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 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.

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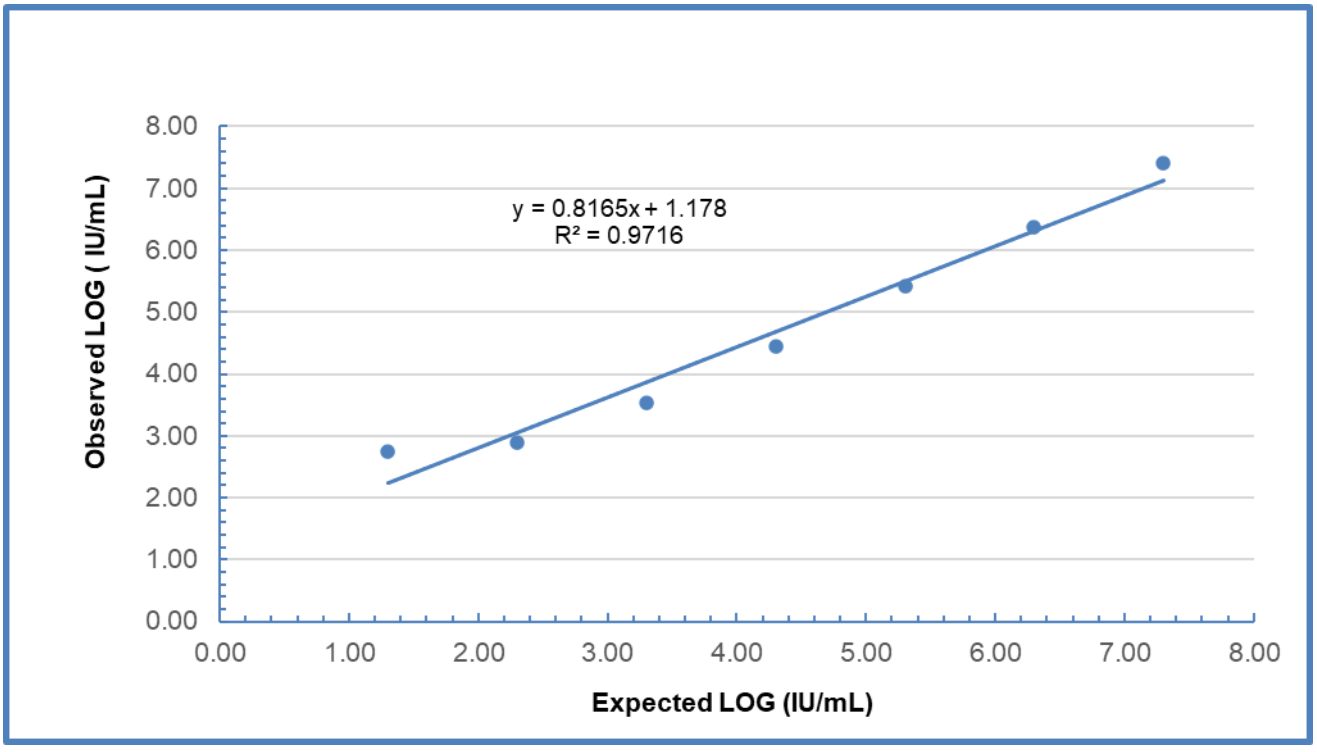

CMV DNA results were obtained using the Roche COBAS® AmpliPrep/COBAS® Taqman® CMV test method. A line of best fit is shown.

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CMV DNA

		Roche COBAS® AmpliPrep/COBAS® Taqman® CMV Test[1]	
Panel Member	**Results (IU/mL)**	**log (IU/mL)**	**log (copies/mL)**
01[2]	**2.62×10^7**	**7.42**	**7.46**
02	**2.33×10^6**	**6.37**	**6.41**
03	**2.69×10^5**	**5.43**	**5.47**
04	**2.79×10^4**	**4.45**	**4.49**
05	**3.39×10^3**	**3.53**	**3.57**
06	**7.83×10^2**	**2.89**	**2.94**
07	**5.57×10^2**	**2.75**	**2.79**
08	TND	TND	TND
09	TND	TND	TND
Test Date		NA	
Test Site		RL	
Test Kit Range		137 to 9,100,000 IU/mL 2.14 to 6.96 log IU/mL	
Test Kit Conversion Factor		1 copy/mL = 0.91 IU/mL, 1 IU/mL = 1.1 copies/mL	
Kit Part Code		NA	
Kit Lot No.		H34292	
Kit Exp. Date		31-Jul-2023	

[1]Results are reported as the mean result of six replicates; positive/reactive results are noted in bold red.
[2]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

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

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche COBAS® AmpliPrep/COBAS® TaqMan® CMV Test (log IU/mL)[1]	% Difference[2]
01	5.70	**5.71**	0.22
02	5.00	**5.09**	1.75
03	4.70	**4.68**	-0.34
04	4.00	**4.00**	0.00
05	3.70	**3.74**	1.10
Test Date		NA	
Test Site		RL	
Test Kit Range		137 to 9,100,000 IU/mL 2.14 to 6.96 log IU/mL	
Test Kit Conversion Factor		1 copy/mL = 0.91 IU/mL, 1 IU/mL = 1.1 copies/mL	
Kit Part Code		NA	
Kit Lot No.		H34292	
Kit Exp. Date		31-Jul-2023	

[1]WHO 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.

[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.