AccuSpan™ CMV DNA Linearity Panel

2410-0174 / Batch #10401694

OVERVIEW

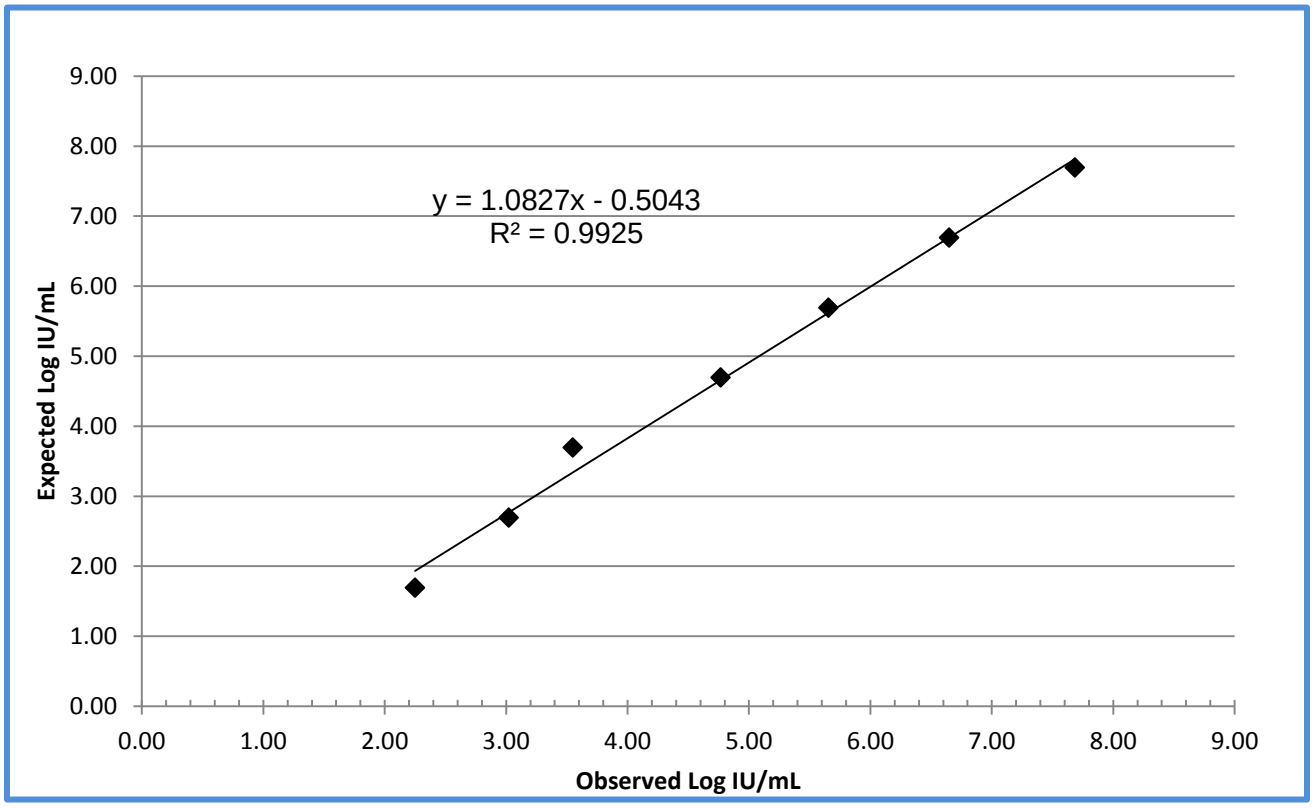
The AccuSpan™ CMV DNA Linearity Panel 2410-0174 / Batch #10401694 is a nine-member panel consisting of seven members representing serial log dilutions of cultured CMV virus, with established reactivity for CMV (Cytomegalovirus) DNA, in CMV DNA negative diluent. This panel also consists of one negative 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 (0.9%) was added as a preservative.

Roche COBAS® AmpliPrep/COBAS® TaqMan® 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; expected results for the WHO standards are the WHO assigned values.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. 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 CMV DNA Linearity Panel Members 1 – 7



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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Panel Member	log IU/mL[1]	Roche COBAS® AmpliPrep/COBAS® TaqMan® CMV Test[1] log copies/mL[1]
01	**7.69**[2]	**7.73**[2]
02	**6.65**	**6.69**
03	**5.66**	**5.70**
04	**4.77**	**4.81**
05	**3.55**	**3.59**
06	**3.02**	**3.06**
07	**2.25**[3]	**2.29**[3]
08	TND	TND
09	TND	TND
Test Date	19-Mar-2019	
Test Site	RL	
Test Kit Range	150 to 10,000,000 copies/mL 137 to 9,100,000 IU/mL	
Test Kit Conversion Factor	1 copy/mL = 0.91 IU/mL, 1 IU/mL = 1.1 copies/mL	
Test Kit Part Code	NA	
Test Kit Lot No.	E18158	
Test Kit Expiration	31-Jul-2020	
Test Kit Regulatory Status	IVD/CE	

[1]Results are reported as the mean result of triplicate testing. Results in red are considered positive.

[2]Panel members were tested at a 1:10 dilution and results were corrected for the dilution factor.

[3]Panel Member 7 tested within the assay limit of quantitation for 2 of 3 replicates. Results are reported as the mean of duplicate testing. Results in red are considered positive.

TND = Target Not Detected; NA = Not Available, RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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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]
Sample B1	5.70	**5.73**	0.6
Sample B2	5.00	**5.22**	4.4
Sample B3	4.70	**4.79**	1.9
Sample B4	4.00	**4.15**	3.8
Sample B5	3.70	**3.87**	4.6
Test Date		19-Mar-2019	
Test Site		RL	
Test Kit Range		150 to 10,000,000 copies/mL 137 to 9,100,000 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.		E18158	
Test Kit Expiration		31-Jul-2020	
Kit Regulatory Status		IVD/CE	

[1]WHO panel was tested in singlet in the same test run as the AccuSpan™ CMV DNA Linearity Panel members. Results in bold red are considered positive.

[2]Percentage difference is how much the observed concentration differs from the expected concentration.
Values calculated for reference only. Some laboratories may use the data to apply a correction factor to the test results.

NA = Not Available, RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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 info@seracare.com or by phone at 508.244.6400.