CMV DNA AccuSpan™ Linearity Panel

2410-0174 / Batch # 10164351

OVERVIEW

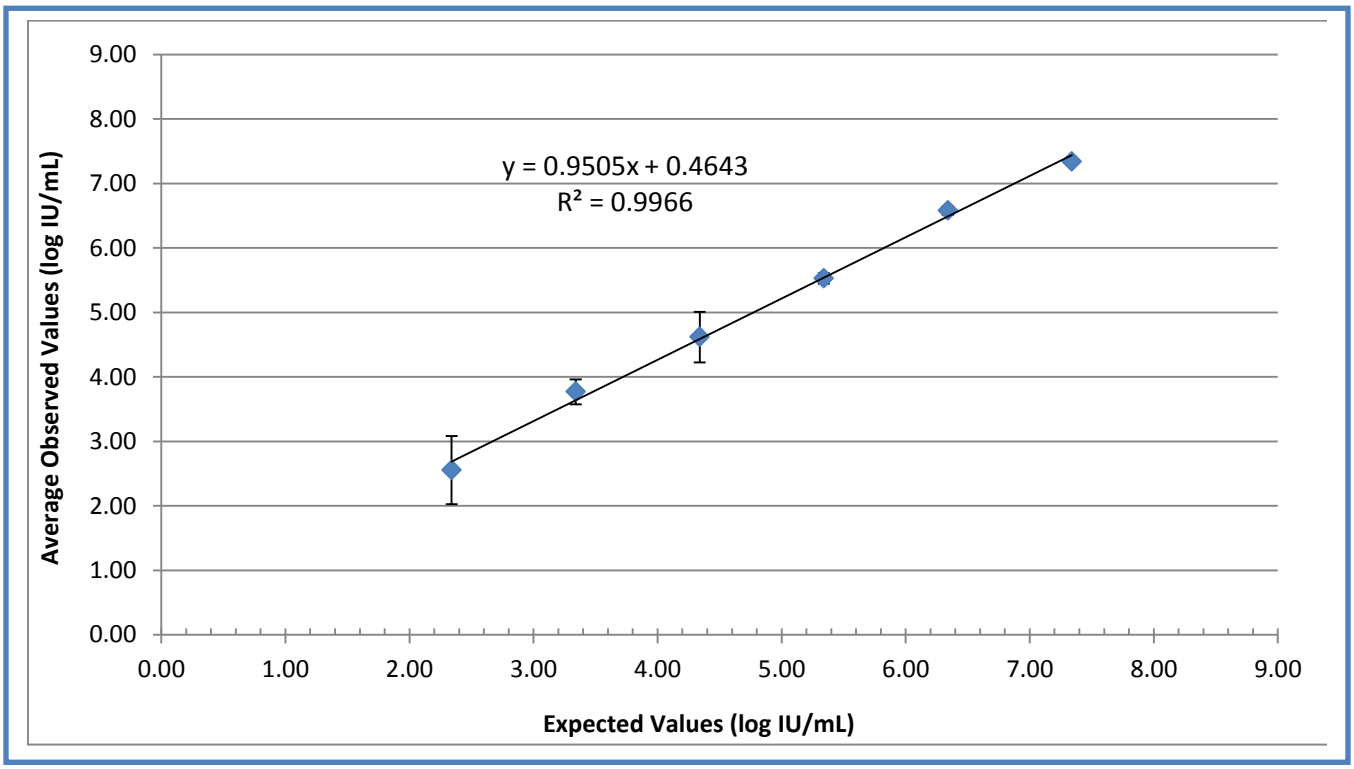
The CMV DNA AccuSpan™ Linearity Panel is a nine member panel made from serial dilutions of a cultured virus with established reactivity for CMV (Cytomegalovirus) DNA. This panel consists of seven members representing serial log dilutions of cultured CMV virus in CMV DNA negative diluent, one negative 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 filtered through a 0.2 micron filter. Sodium azide (0.9%) 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 CMV DNA AccuSpan 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.

CMV DNA AccuSpan Linearity Panel Members 1-6



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

CMV DNA AccuSpan™ Linearity Panel

2410-0174 / Batch # 10164351

CMV DNA AccuSpan Linearity Panel

CMV DNA AccuSpan Linearity Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® CMV Test[1] log IU/mL[1]	log copies/mL[1]
01	**7.34**[2]	**7.38**[2]
02	**6.58**	**6.63**
03	**5.53**	**5.57**
04	**4.62**	**4.79**
05	**3.77**	**3.84**
06	**2.55**	**2.82**
07	<137 IU/mL[3]	<150 copies/mL[3]
08	TND	TND
09	TND	TND

Test Date	17-Feb-2016
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	N/A
Test Kit Lot No.	W1138300000
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]CMV DNA detected; calculated value is below the limit of detection of 137 IU/mL or 150 copies/mL.

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

CMV DNA AccuSpan™ Linearity Panel

2410-0174 / Batch # 10164351

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 c1	5.70	**5.89**	3.29
Sample c2	5.00	**5.14**	2.86
Sample c3	4.70	**4.96**	5.50
Sample c4	4.00	**4.16**	3.88
Sample c5	3.70	**3.87**	4.51

Test Date	17-Feb-16
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	N/A
Kit Lot No.	W1138300000
Kit Regulatory Status	IVD/CE

[1]WHO panel was tested in singlet in the same test run as the CMV DNA AccuSpan™ 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.

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

ASK ABOUT RELATED SERACARE PRODUCTS

- AccuTrak™ Qualification Panels
- Disease State Biological Materials
- ACCURUN® Independent Quality Controls
- SeraCon™ and Basematrix Processed Plasma