HIV-1 RNA AccuSpan™ Linearity Panel

2410-0221 / Batch # 10220166

OVERVIEW

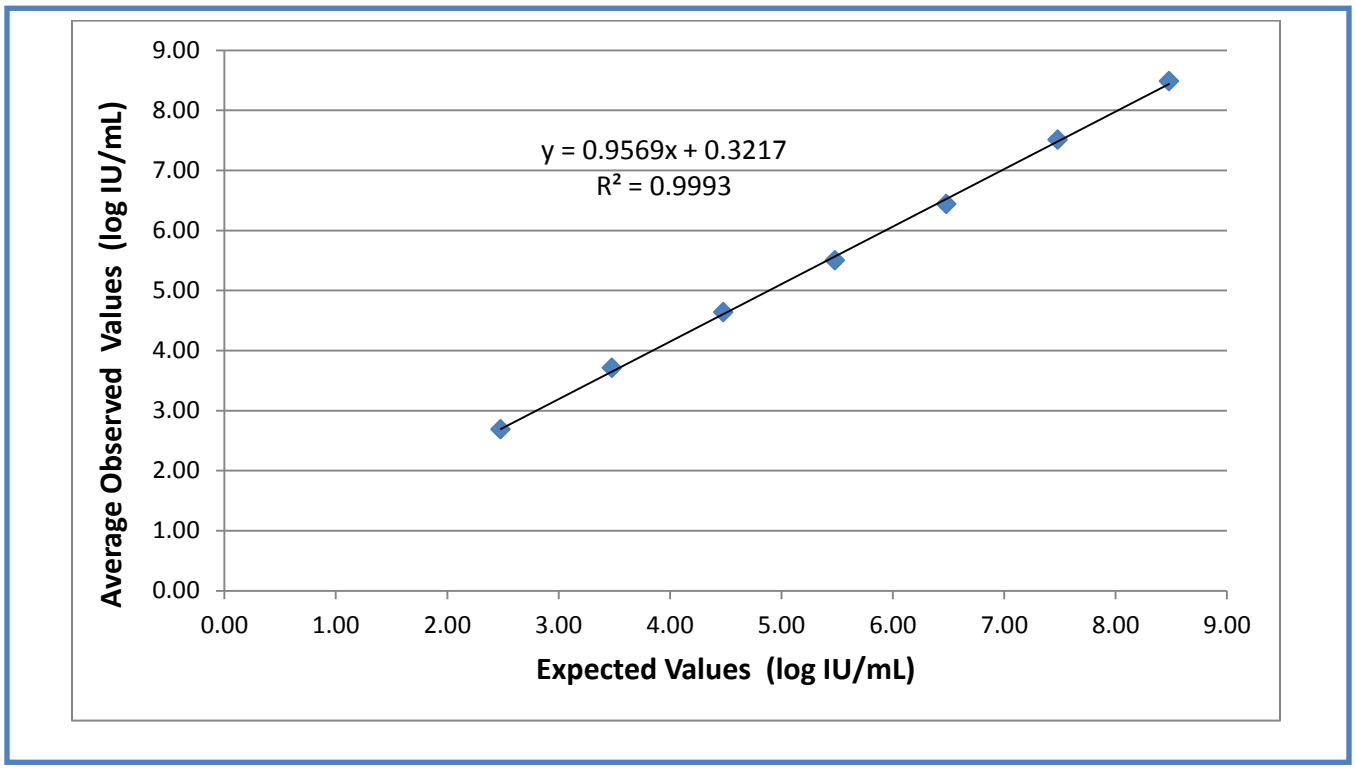
The HIV-1 RNA AccuSpan™ Linearity Panel is a ten member panel made from serial dilutions of a cultured virus with established reactivity for HIV-1 (Human Immunodeficiency Virus 1, 8E5) RNA. This panel consists of eight members representing serial log dilutions of cultured HIV-1 virus in HIV-1 RNA negative 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 µm filter. Sodium azide (0.09%) 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 HIV-1 RNA 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.

HIV-1 RNA AccuSpan Linearity Panel Members 1-7



HIV-1 RNA results were obtained using the Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Version 2.0 test method. Results are the mean of three replicates. A line of best fit is shown.

HIV-1 RNA AccuSpan™ Linearity Panel

2410-0221 / Batch # 10220166

HIV-1 RNA AccuSpan Linearity Panel

HIV-1 RNA AccuSpan Linearity Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Version 2.0[1]		Abbott *m*2000 RealTi*me* HIV-1[1]	
	log IU/mL	log copies/mL	log IU/mL	log copies/mL
01	**8.48**[2]	**8.25**[2]	**8.71**	**8.46**
02	**7.51**[3]	**7.28**[3]	**7.71**	**7.47**
03	**6.44**	**6.21**	**6.82**	**6.57**
04	**5.50**	**5.27**	**5.73**	**5.49**
05	**4.64**	**4.41**	**4.74**	**4.50**
06	**3.71**	**3.48**	**3.67**	**3.43**
07	**2.68**	**2.45**	**2.86**	**2.62**
08	**1.67**, TND[4]	**1.44**, TND[4]	**WR**[5]	**WR**[5]
09	TND	TND	TND	TND
10	TND	TND	TND	TND

Test Date	19-Sep-2016	14-Sep-2016
Test Site	RL	RL
Test Kit Range	20 to 10,000,000 copies/mL	40 to 10,000,000 copies/mL
Test Kit Conversion Factor	1 copy = 1.7 IU, 1 IU = 0.6 copies	1 copy = 1.74 IU, 1 IU = 0.57 copies
Test Kit Part Code	NA	6L18-90
Test Kit Lot No.	W16318	468342
Test Kit Regulatory Status	IVD/CE	IVD/CE

[1]Results are reported as the mean result of three replicates. Both log IU/mL and log copies/mL are shown. Results in bold red are considered positive.
[2]Panel members were tested at a 1:100 dilution and results were corrected for the dilution factor.
[3]Panel members were tested at a 1:10 dilution and results were corrected for the dilution factor.
[4]HIV-1 RNA detected for two replicates and averaged; one replicate was below the limit of detection of 20 copies/mL.
[5]HIV-1 RNA detected, weakly reactive (WR), less than 40 copies/mL.

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

HIV-1 RNA AccuSpan™ Linearity Panel

2410-0221 / Batch # 10220166

WHO International Standard 3rd HIV-1 International Standard (NIBSC code: 10/152)

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Version 2.0 (log IU/mL)[1]	% Difference[2]
Sample 1	4.70	**4.69**	-0.10
Sample 2	4.00	**4.00**	-0.06
Sample 3	3.70	**3.52**	-4.74
Sample 4	3.00	**2.86**	-4.74

Test Date	19-Sep-2016
Test Site	RL
Test Kit Range	20 to 10,000,000 copies/mL
Test Kit Conversion Factor	1 copy = 1.7 IU, 1 IU = 0.6 copies
Kit Part Code	NA
Kit Lot No.	W16318
Kit Regulatory Status	IVD/CE

[1]WHO panel was tested in the same test run as the HIV-1 AccuSpan™ Linearity Panel members. Samples were run in singlet. 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; NA = Not Available; 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