AccuSpan™ HIV-1 RNA Linearity Panel

2410-0221 / Batch #10383902

OVERVIEW

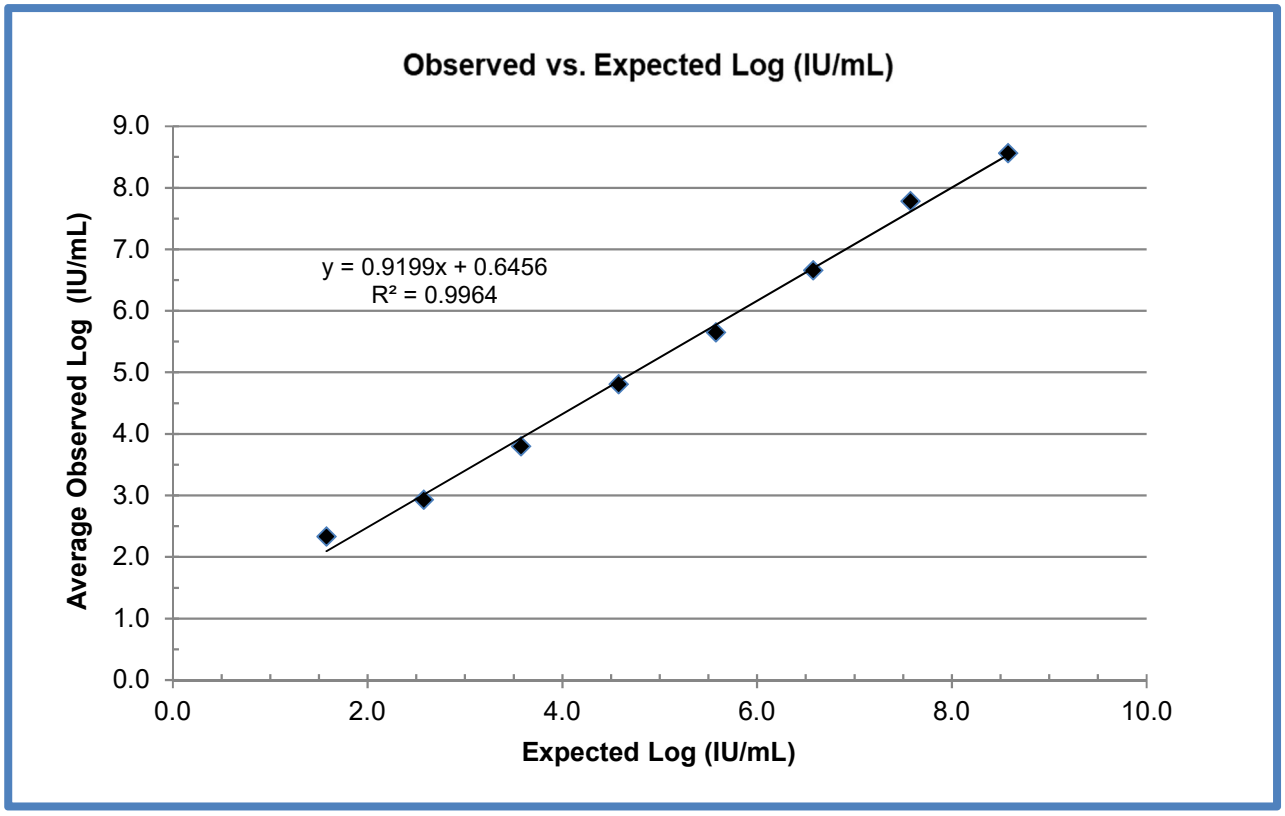
AccuSpan™ HIV-1 RNA Linearity Panel (2410-0221 / Batch #10383902) is a ten member panel made from serial dilutions of a cultured virus with established reactivity for HIV-1 (Human Immunodeficiency Virus 1, 8E5) RNA. This panel consists of eight members representing serial log dilutions of cultured HIV-1 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 AccuSpan HIV-1 RNA 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™ HIV-1 RNA Linearity Panel Members 1-8



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.

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HIV-1 RNA

	Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Version 2.0		Abbott m2000 RealTime HIV-1	
Panel Member	**(log IU/mL)[1]**	**(log copies/mL)[1]**	**(log IU/mL)[1]**	**(log copies/mL)[1]**
01	**8.56**[2]	**8.35**[2]	**ALR**	**ALR**
02	**7.78**[3]	**7.55**[3]	**ALR**	**ALR**
03	**6.66**	**6.44**	**6.64**	**6.40**
04	**5.65**	**5.43**	**5.62**	**5.38**
05	**4.81**	**4.58**	**4.53**	**4.29**
06	**3.80**	**3.57**	**3.55**	**3.31**
07	**2.93**	**2.71**	**2.69**	**2.45**
08	**2.33**	**2.10**	**2.35**	**2.11**
09	TND	TND	TND	TND
10	TND	TND	TND	TND
Test Date	06-Dec-2018		06-Dec-2018	
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 = 0.58 copies	
Test Kit Part Code	NA		NA	
Test Kit Lot No.	E1139200000		488989	
Test Kit Exp. Date	31-Mar-2020		30-Nov-2019	
Test Kit Regulatory Status	IVD/CE		IVD	

[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 member was tested at a 1:100 and 1:1000 dilution and results were corrected for the dilution factor.
[3]Panel member was tested at a 1:10 dilution and results were corrected for the dilution factor.
TND = Target Not Detected; ALR = Above Linear Range
RL = Reference Lab; NA = Not Available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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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	**4.68**	-0.38
Sample 2	4.00	**4.09**	2.32
Sample 3	3.70	**3.81**	3.01
Sample 4	3.00	**3.01**	0.36
Test Date		06-Dec-2018	
Test Site		RL	
Test Kit Range		20 to 10,000,000 copies/mL	
Test Kit Conversion		1 copy = 1.7 IU, 1 IU = 0.6 copies	
Test Kit Part Code		NA	
Test Kit Lot No.		E1139200000	
Test Kit Exp. Date		31-Mar-2020	
Test Kit Regulatory Status		IVD/CE	

[1]WHO panel was tested in the same test run as the AccuSpan™ HIV-1 RNA Linearity Panel members. Results are reported as the mean result of three replicates. 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. 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.