AccuSpan™ HIV-1 RNA Linearity Panel

2410-0221 / Batch #10736804

OVERVIEW

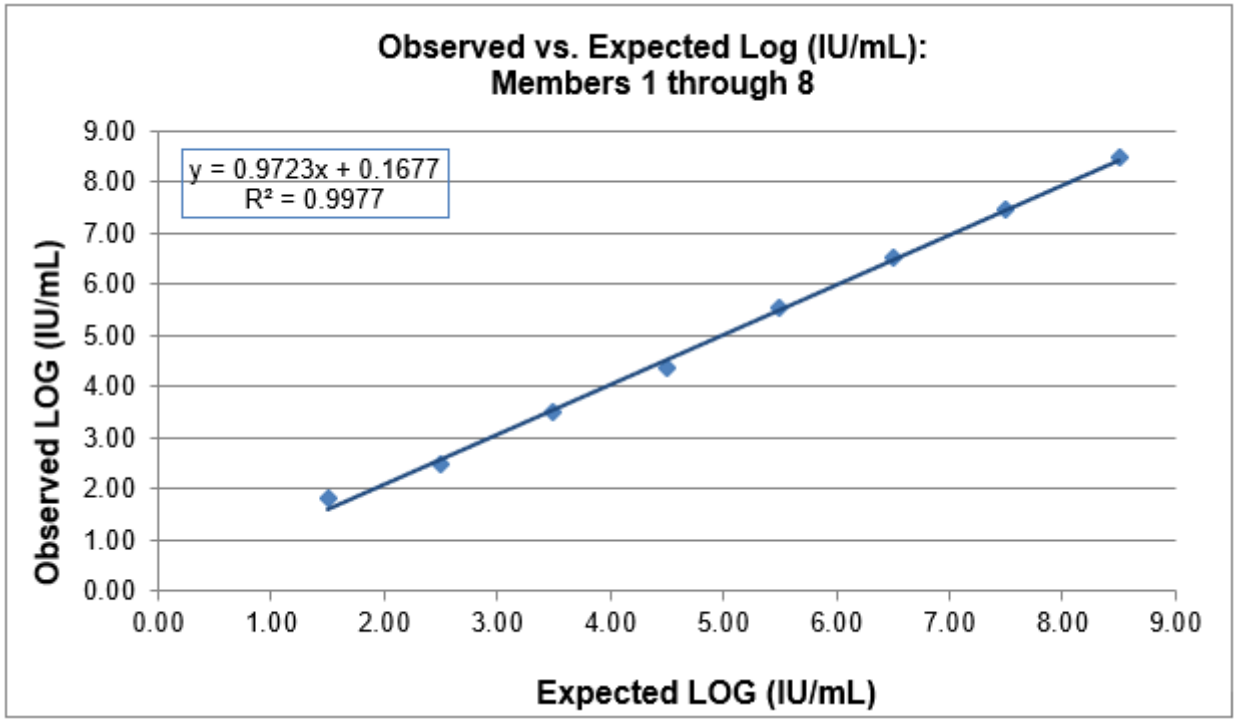
AccuSpan™ HIV-1 RNA Linearity Panel 2410-0221 / Batch #10736804 is a ten-member panel made from serial dilutions of a cultured virus with established reactivity for HIV-1 (Human Immunodeficiency Virus 1, 8E5) RNA. This panel consists of eight members representing serial log dilutions of cultured HIV-1 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; 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: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for HIV-1 RNA; all were found negative for anti-HCV and HBsAg. This does not ensure the absence of these or other human pathogens.

AccuSpan™ HIV-1 RNA Linearity Panel Members 1-8



HIV-1 RNA results were obtained using the Roche cobas® 5800/6800/8800 HIV-1 RNA 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® 5800/6800/8800 HIV-1 RNA[1]			
Panel Member	**Results (copies/mL)**	**(log copies/mL)**	**Results (IU/mL)**	**(log IU/mL)**
01[2]	**1.90E+08**	**8.28**	**3.17E+08**	**8.50**
02[3]	**1.74E+07**	**7.24**	**2.90E+07**	**7.46**
03	**2.06E+06**	**6.30**	**3.43E+06**	**6.52**
04	**2.16E+05**	**5.32**	**3.59E+05**	**5.54**
05	**1.49E+04**	**4.15**	**2.48E+04**	**4.37**
06	**2.00E+03**	**3.28**	**3.33E+03**	**3.50**
07	**1.96E+02**	**2.29**	**3.27E+02**	**2.51**
08	**4.50E+01**	**1.61**	**7.51E+01**	**1.83**
09	TND	TND	TND	TND
10	TND	TND	TND	TND
Test Date	16-May-2025			
Test Site	RL			
Test Kit Range	20 to 10,000,000 copies/mL 1.30 to 7.00 log copies/mL 33 to 16,700,000 IU/mL 1.52 to 7.22 log IU/mL			
Test Kit Conversion Factor	1 copy = 1.70 IU 1 IU = 0.60 copies			
Kit Part Code	NA			
Kit Lot No.	M08892			
Kit Exp. Date	01-Apr-2026			

[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 #1 was tested at a 1:100 dilution and results were corrected for the dilution factor.
[3]Panel member #2 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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HIV-1 RNA

	Abbott Alinity m HIV-1 RNA[1]			
Panel Member	**Results (copies/mL)**	**(log copies/mL)**	**Results (IU/mL)**	**(log IU/mL)**
01[2]	**1.40E+08**	**8.14**	**2.29E+08**	**8.36**
02[3]	**1.57E+07**	**7.19**	**2.57E+07**	**7.41**
03	**1.44E+06**	**6.16**	**2.36E+06**	**6.37**
04	**1.39E+05**	**5.14**	**2.28E+05**	**5.36**
05	**1.42E+04**	**4.14**	**2.32E+04**	**4.36**
06	**1.60E+03**	**3.20**	**2.63E+03**	**3.42**
07	**1.74E+02**	**2.23**	**2.86E+02**	**2.45**
08	**3.87E+01**	**1.51**	**6.34E+01**	**1.73**
09	TND	TND	TND	TND
10	TND	TND	TND	TND
Test Date	02-May-2025			
Test Site	RL			
Test Kit Range	20 to 10,000,000 copies/mL 1.30 to 7.00 log copies/mL 32.6 to 16,300,000 IU/mL 1.51 to 7.21 log IU/mL			
Test Kit Conversion Factor	1 copy = 1.63 IU 1 IU = 0.61 copies			
Kit Part Code	NA			
Kit Lot No.	409888			
Kit Exp. Date	16-Apr-2026			

[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 #1 was tested at a 1:100 dilution and results were corrected for the dilution factor.
[3]Panel member #2 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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3rd WHO International HIV-1 RNA Standard (10/152)

Sample ID	Expected Values (log IU/mL)	Roche cobas® 5800/6800/8800 HIV-1 RNA[1] (log IU/mL)	% Difference[2]
Sample 2	4.70	**4.92**	4.6
Sample 3	4.00	**4.06**	1.6
Sample 4	3.70	**3.83**	3.4
Sample 5	3.00	**3.03**	1.1
Test Date		16-May-2025	
Test Site		RL	
Test Kit Range		20 to 10,000,000 copies/mL 1.30 to 7.00 log copies/mL 33 to 16,700,000 IU/mL 1.52 to 7.22 log IU/mL	
Test Kit Conversion Factor		1 copy = 1.70 IU 1 IU = 0.60 copies	
Kit Part Code		NA	
Kit Lot No.		M08892	
Kit Exp. Date		01-Apr-2026	

[1]WHO standard dilutions were tested in the same test run as the AccuSpan™ HIV-1 RNA Linearity Panel members. 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.