

AccuSpan™ HCV RNA Linearity Panel

2410-0327 / Batch #10716083

OVERVIEW

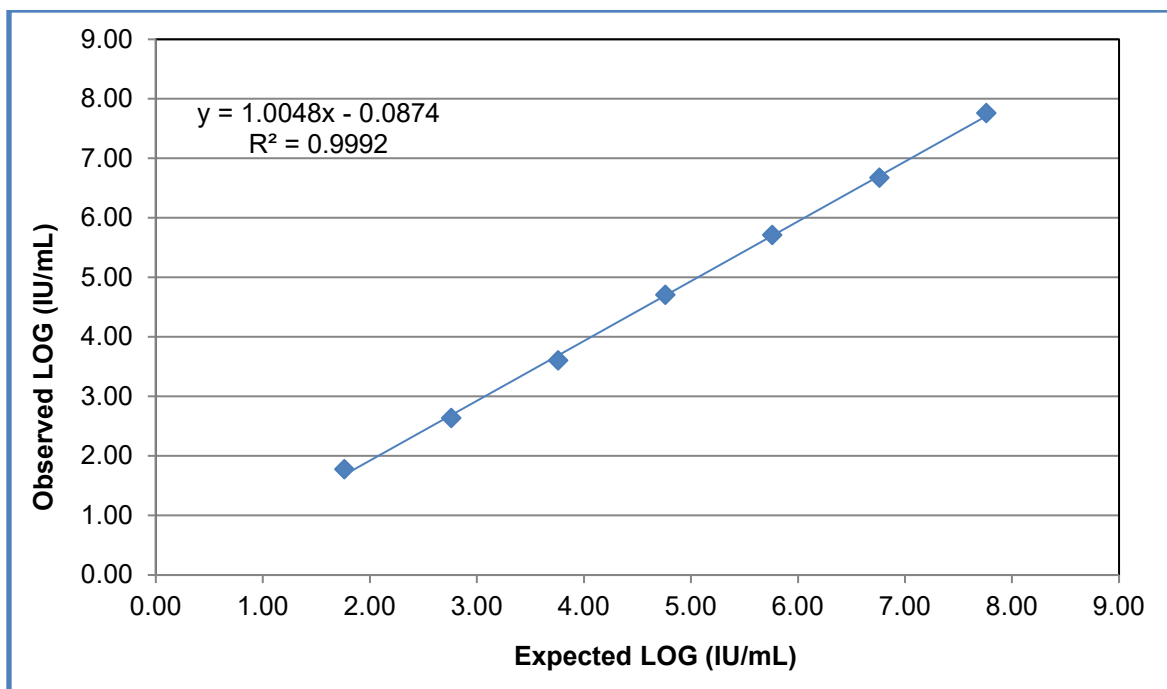
AccuSpan™ HCV RNA Linearity Panel 2410-0327 / Batch #10716083 is an eight-member panel made from serial dilutions of high titer recombinant Hepatitis C virus (genotype 1b) with established reactivity for HCV RNA and one negative member. This panel consists of seven members representing serial log dilutions of AccuPlex recombinant HCV in negative diluent and one negative member prepared from the diluent. The diluent was prepared from pooled K3 EDTA plasma that was filtered through a 0.2 micron filter. Sodium azide (0.09%) was added as a preservative.

Results are reported for each panel member on specific test methods. Linearity is shown graphically by plotting observed results against expected results. The WHO International Standard was tested in the same run as the AccuSpan HCV 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: These materials have not been treated and should be considered biohazardous. Follow Universal Precautions.

AccuSpan™ HCV RNA Linearity Panel



HCV RNA results were obtained using Roche cobas® 6800/8800 HCV test method. Results are the mean of three replicates. A line of best fit is shown.

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HCV DNA¹

Panel Member	Roche cobas® 6800/8800 HCV Test (IU/mL)	Roche cobas® 6800/8800 HCV Test (log IU/mL)
01*	5.74 x 10⁷	7.76
02	4.79 x 10⁶	6.67
03	5.17 x 10⁵	5.71
04	5.07 x 10⁴	4.70
05	4.03 x 10³	3.60
06	4.37 x 10²	2.63
07	6.17 x 10¹	1.78
08	TND	TND
Test Date	27-Aug-2024	
Test Site	RL	
Test Kit Range	15 – 100,000,000 IU/mL 1.18 – 8.00 log IU/mL	
Kit Part Code	NA	
Kit Lot No.	NA	
Kit Exp. Date	NA	

¹Results are reported as the mean result of triplicate testing; positive/reactive results are noted in bold red.

*Panel Member #1 was tested at a 1:100 dilution and results were corrected for the dilution factor.

TND = Target Not Detected; RL = Reference Lab; NA = Not Available

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HCV DNA¹

Panel Member	Abbott Alinity m HCV Assay (IU/mL)	Abbott Alinity m HCV Assay (log IU/mL)
01*	1.73 x 10⁷	7.23
02	2.06 x 10⁶	6.31
03	1.57 x 10⁵	5.19
04	1.46 x 10⁴	4.15
05	1.21 x 10³	3.05
06	1.64 x 10²	2.22
07	BLD, 28, BLD	BLD, 1.45, BLD
08	TND	TND
Test Date	29-Aug-2024	
Test Site	RL	
Test Kit Range	12 – 100,000,000 IU/mL 1.08 – 8.00 log IU/mL	
Kit Part Code	NA	
Kit Lot No.	400201	
Kit Exp. Date	11-Dec-2025	

¹Results are reported as the mean result of triplicate testing; positive/reactive results are noted in bold red.

*Panel Member #1 was tested at a 1:100 dilution and results were corrected for the dilution factor.

BLD = Detected but below the lower limit of quantitation; TND = Target Not Detected; RL = Reference Lab; NA = Not Available

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6th WHO HCV RNA International Standard (18/184)

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche cobas® 6800/8800 HCV Test (log IU/mL) ¹	% Difference ²
Sample 01	4.70	4.59	-2.3
Sample 02	4.00	3.99	-0.3
Sample 03	3.70	3.69	-0.3
Sample 04	3.00	2.96	-1.5
Test Date		27-Aug-2024	
Test Site		RL	
Test Kit Range		15 – 100,000,000 IU/mL 1.18 – 8.00 log IU/mL	
Kit Part Code		NA	
Kit Lot No.		NA	
Kit Exp. Date		NA	

¹WHO panel was tested in the same test run as the AccuSpan™ HCV RNA Linearity Panel members. Samples were run in singlet. Positive/reactive results are noted in bold red.

²Percentage difference is how much the observed log concentration differs from the expected log 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.