

AccuSpan™ HCV RNA **Linearity Panel** 2410-0166 / Batch #10780553

OVERVIEW

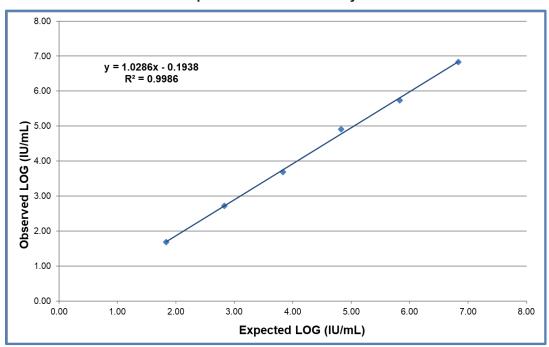
The AccuSpan™ HCV RNA Linearity Panel (2410-0166 / Batch #10780553) is an eight-member panel made from serial dilutions of high titer HCV positive plasma with established reactivity for HCV (Hepatitis C) RNA. This panel consists of seven members representing serial log dilutions of HCV positive plasma in HCV RNA negative diluent and one negative member prepared from the diluent. The diluent was prepared from normal human 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; expected results for the WHO standards 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 the Roche cobas® 5800/6800/8800 HCV test method. Results are the mean of three replicates. A line of best fit is shown.

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15130-01



AccuSpan[™] HCV RNA Linearity Panel 2410-0166 / Batch #10780553

HCV RNA¹

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Panel Member	Roche cobas [®] 5800/6800/8800 HCV Test (IU/mL)	Roche cobas [®] 5800/6800/8800 HCV Test (log IU/mL)	Abbott Alinity m HCV Test (IU/mL)	Abbott Alinity m HCV Test (log IU/mL)
01 ²	6.88E+06	6.83	7.01E+06	6.83
02	5.53E+05	5.74	4.50E+05	5.65
03	8.10E+04	4.91	5.90E+04	4.77
04	4.88E+03	3.69	4.10E+03	3.61
05	5.26E+02	2.72	4.45E+02	2.64
06	4.95E+01	1.68	5.17E+01	1.71
07	<15	<1.18	TND	TND
08	TND	TND	TND	TND
Test Date	17-Nov-2025	17-Nov-2025	30-Oct-2025	30-Oct-2025
Test Site	RL	RL	RL	RL
Test Kit Range	15 to 100,000,000 IU/mL 1.18 to 8.00 log IU/mL	15 to 100,000,000 IU/mL 1.18 to 8.00 log IU/mL	12 to 100,000,000 IU/mL 1.08 to 8.00 log IU/mL	12 to 100,000,000 IU/mL 1.08 to 8.00 log IU/mL
Kit Part Code	NA	NA	NA	NA
Kit Lot No.	M27638	M27638	413643	413643
Kit Exp. Date	01-Dec-2026	01-Dec-2026	20-Feb-2027	20-Feb-2027

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

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²Panel member #1 was tested at a 1:10 dilution and results were corrected for dilution factor.

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



AccuSpan[™] HCV RNA Linearity Panel 2410-0166 / Batch #10780553

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

	Franciska d Walana	Roche cobas® 6800/8800			
Panel Member	Expected Values (log IU/mL)	HCV Test (log IU/mL)¹	% Difference ²		
01	4.70	4.74	0.8		
02	4.00	3.99	-0.3		
03	3.70	3.63	-1.8		
04	3.00	3.03	1.1		
Test Date	17-Nov-2025				
Test Site	RL				
Test Kit Range	15 to 100,000,000 IU/mL 1.18 to 8.00 log IU/mL				
Kit Part Code	NA				
Kit Lot No.	M27638				
Kit Exp. Date	01-Dec-2026				

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.

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.

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²Percentage 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