AccuSpan™ HCV RNA Linearity Panel

PHW805 (2410-0166) / Batch #10338244

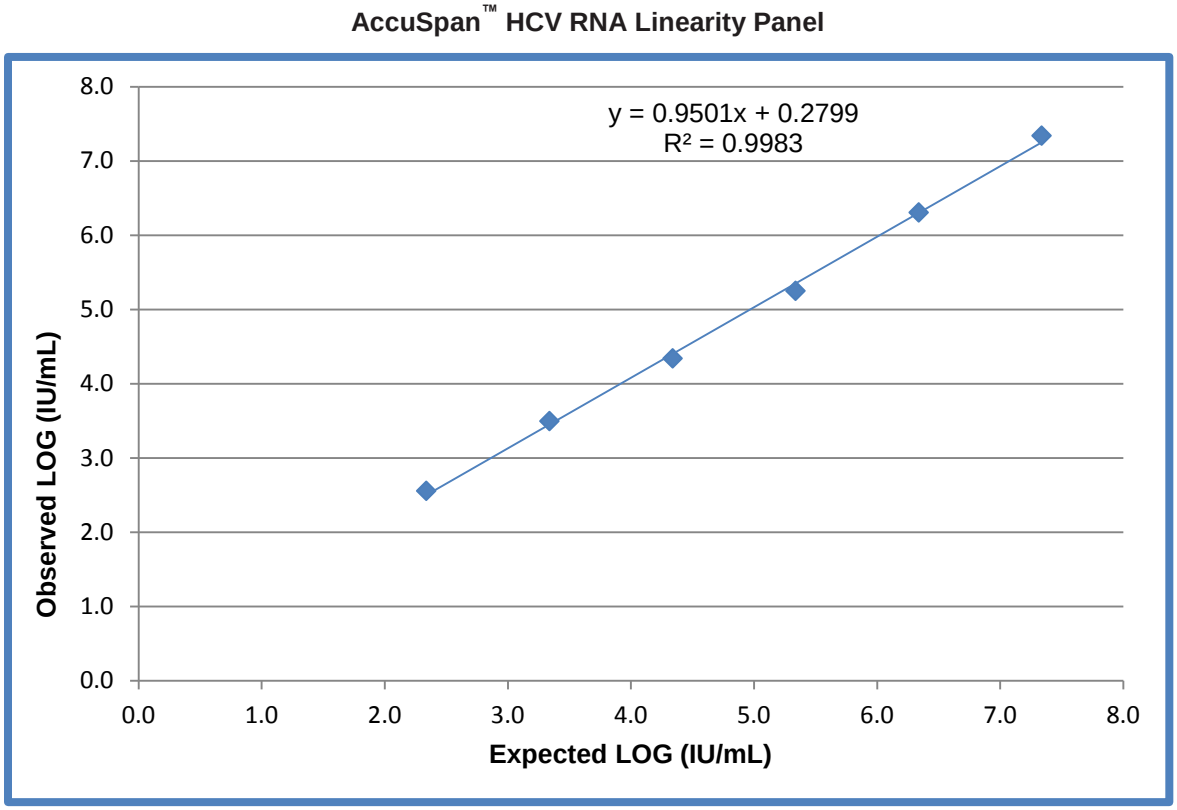
OVERVIEW

The AccuSpan™ HCV RNA Linearity Panel 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 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.



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

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HCV RNA

Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Version 2.0[1,2] (log IU/mL)	Abbott *m*2000 RealTi*me* HCV[1,2] (log IU/mL)
01	**7.34**	**7.17**
02	**6.30**	**6.18**
03	**5.25**	**5.15**
04	**4.34**	**4.16**
05	**3.49**	**3.18**
06	**2.55**	**2.27**
07	**1.26**[3]; <15	**1.35**
08	TND	TND
Test Date	26-Apr-2018	26-Apr-2018
Test Site	RL	RL
Test Kit Range	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
Test Kit Part Code	NA	NA
Test Kit Lot No.	Y2328700000	480647
Test Kit Regulatory Status	IVD/CE	IVD/CE

[1]Results are reported as log international units per mL (log IU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as the mean result of triplicate testing.
[3]One replicate tested positive at 1.26 log IU/mL, two replicates tested below the assay limit of quantitation <15 IU/mL.
RL = Reference Lab; NA = Not available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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4th WHO International HCV RNA Standard (06/102)

Sample ID	Expected Values (log IU/mL)	Observed Values on Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Version 2.0 (log IU/mL)[1]	% Difference[2]
Sample 1	4.70	**4.56**	-2.86
Sample 2	4.00	**3.90**	-2.54
Sample 3	3.70	**3.63**	-1.99
Sample 4	3.00	**3.00**	-0.16
Test Date		26-Apr-2018	
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.		Y2328700000	
Kit Regulatory Status		IVD/CE	

[1]WHO 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.
[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
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.