HCV RNA AccuSpan™ Linearity Panel

2410-0166 (PHW805) / Batch # 10159731

OVERVIEW

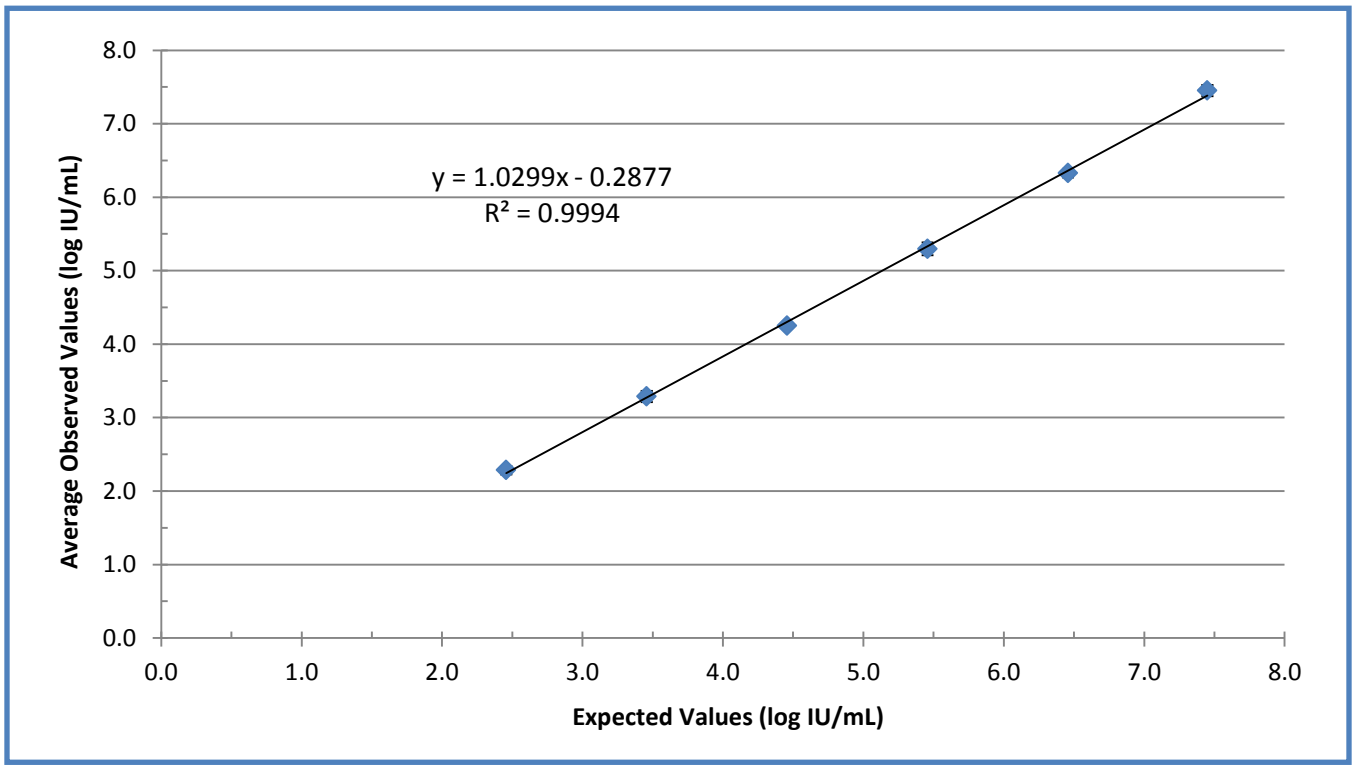
The HCV RNA AccuSpan™ Linearity Panel is an eight member panel made from serial dilutions of high titer HCV positive plasma with established reactivity for HCV (Hepatitis C) RNA. This panel consists of seven members representing serial log dilutions of HCV positive plasma in HCV RNA negative diluent 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 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 HCV RNA AccuSpan 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 AccuSpan Linearity Panel Members 1-6



HCV RNA results were obtained using the Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Version 2.0 test method. Results are the mean of six replicates. A line of best fit is shown.

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HCV RNA AccuSpan Linearity Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Version 2.0[1] log IU/mL	Abbott *m*2000 RealTi*me* HCV[2] log IU/mL
01	**7.45**	**7.22**
02	**6.33**	**6.13**
03	**5.30**	**5.17**
04	**4.25**	**4.09**
05	**3.29**	**3.04**
06	**2.28**	**2.18**
07	<15 IU/mL[3]	**1.22**
08	TND	TND

Test Date	28-Jan-2016, 31-Jan-2016	27-Jan-2016
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	N/A	N/A
Test Kit Lot No.	W07687	463798
Test Kit Regulatory Status	IVD/CE	IVD/CE

[1]Results are reported as the mean result of six replicates. Results in bold red are considered positive.

[2]Results are reported as the mean result of triplicate testing. Results in bold red are considered positive.

[3]HCV RNA detected, calculated IU/mL are below the limit of detection of 15 IU/mL.

TND = Target Not Detected

RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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WHO International Standard 4th HCV RNA International Standard (NIBSC code: 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 A-1-A	4.70	**4.55**	-3.23
Sample A-2-A	4.00	**3.88**	-2.94
Sample A-3-A	3.70	**3.46**	-6.36
Sample A-4-A	3.00	**2.96**	-1.37

Test Date	31-Jan-2016
Test Site	RL
Test Kit Range	15 to 100,000,000 IU/mL 1.18 to 8.00 log IU/mL
Kit Part Code	N/A
Kit Lot No.	W07687
Kit Regulatory Status	IVD/CE

[1]WHO panel was tested in the same test run as the HCV RNA AccuSpan™ Linearity Panel members. Samples were run in singlet. Results in bold red are considered positive.
[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

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- HCV RNA Genotype AccuTrak™ Qualification Panel
- HCV RNA Disease State Biological Materials
- ACCURUN® Independent Quality Controls
- SeraCon™ and Basematrix Processed Plasma