# AccuSpan™ HCV RNA Linearity Panel

PHW805 (2410-0166) / Batch #10408955

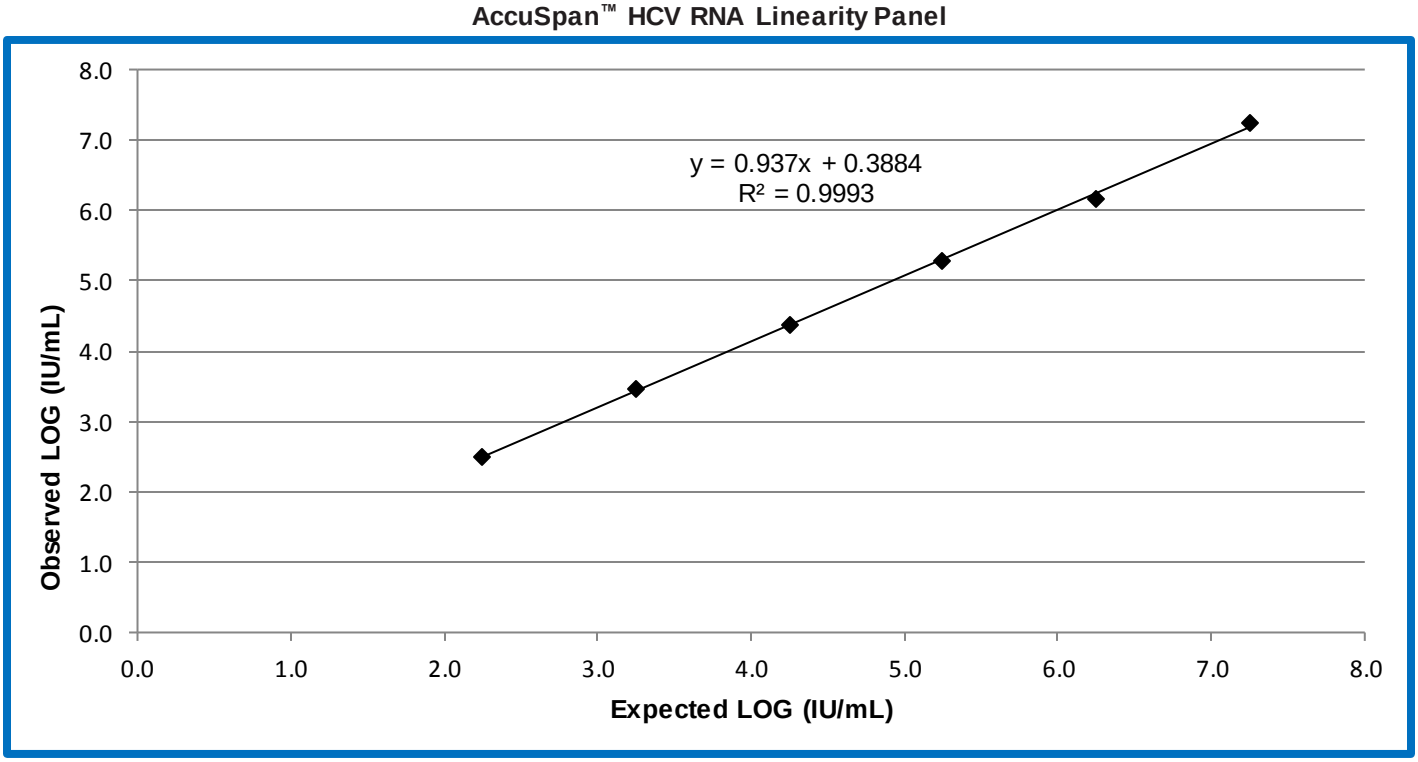
## OVERVIEW

The AccuSpan™ HCV RNA Linearity Panel PHW805 (2410-0166) / Batch #10408955 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. A series of dilutions from the WHO International Standard was tested in the same run as the AccuSpan HCV RNA Linearity Panel members. Both expected and observed results from the dilutions series are reported; the expected values from the WHO standards are the dilution estimated 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. Member #1 is the mean result of triplicate testing from a dilution of 1:10 and 1:100. Member #2 - #6 is the mean of three replicates. Member #7 is the average of 2 results as one replicate tested below the assay limit of quantitation. 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 RealTime HCV[1,2] (log IU/mL) |
|---|---|---|
| 01 | **7.25**[3] | **7.20** |
| 02 | **6.17** | **6.25** |
| 03 | **5.28** | **5.30** |
| 04 | **4.37** | **4.28** |
| 05 | **3.46** | **3.26** |
| 06 | **2.50** | **2.35** |
| 07 | **1.42**[4], <15 | **1.42** |
| 08 | TND | TND |
| Test Date | 02-May-2019 | 02-May-2019 |
| Test Site | RL | RL |
| Test Kit Range | 15 to 100,000,000 IU/mL<br>1.18 to 8.00 log IU/mL | 12 to 100,000,000 IU/mL<br>1.08 to 8.00 log IU/mL |
| Test Kit Part Code | NA | NA |
| Test Kit Lot No. | E2156800000 | NA |

[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]Results are reported as the mean result of triplicate testing from a dilution of 1:10 and 1:100.
[4]Results are reported as the mean result of two replicates, one replicate tested below the assays limit of quantitation and the result is displayed independently.
RL = Reference Lab; NA = Not available

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**5th WHO International HCV RNA Standard (14/150)**

| 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 | 4.60 | **4.44** | -3.58 |
| Sample 2 | 4.00 | **3.92** | -1.97 |
| Sample 3 | 3.70 | **3.96** | 6.94 |
| Sample 4 | 3.00 | **3.22** | 7.43 |
| Test Date | | 02-May-2019 | |
| Test Site | | RL | |
| Test Kit Range | | 15 to 100,000,000 IU/mL<br>1.18 to 8.00 log IU/mL | |
| Kit Part Code | | NA | |
| Kit Lot No. | | E2156800000 | |

[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

**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.**