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.

HIV-1 RNA AccuSpan Linearity Panel Members 1-6

\[ y = 0.9468x + 0.2719 \]
\[ R^2 = 0.9983 \]

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.
### HCV RNA AccuSpan™ Linearity Panel

HCV RNA AccuSpan™ Linearity Panel 2410-0166 (PHW805) / Batch # 10220359

<table>
<thead>
<tr>
<th>HCV RNA AccuSpan Linearity Panel Member</th>
<th>Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Version 2.0&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Abbott m2000 RealTime HCV&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>log IU/mL</td>
<td>log IU/mL</td>
</tr>
<tr>
<td>01</td>
<td>7.21&lt;sup&gt;2&lt;/sup&gt;</td>
<td>7.16</td>
</tr>
<tr>
<td>02</td>
<td>6.06</td>
<td>6.05</td>
</tr>
<tr>
<td>03</td>
<td>5.14</td>
<td>5.13</td>
</tr>
<tr>
<td>04</td>
<td>4.26</td>
<td>4.21</td>
</tr>
<tr>
<td>05</td>
<td>3.32</td>
<td>3.07</td>
</tr>
<tr>
<td>06</td>
<td>2.40</td>
<td>2.23</td>
</tr>
<tr>
<td>07</td>
<td>1.46, Detected at &lt; 1.18&lt;sup&gt;3&lt;/sup&gt;</td>
<td>1.19, Detected at &lt; 1.08&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>08</td>
<td>ND</td>
<td>ND</td>
</tr>
</tbody>
</table>

**Test Date**
- 22-Sep-16, 23-Sep-16

**Test Site**
- 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

**Test Kit Lot No.**
- X00055
- 468366

**Test Kit Regulatory**
- IVD/CE

---

<sup>1</sup>Results are reported as the mean result of three replicates. Results in bold red are considered positive.

<sup>2</sup>Panel member was tested at a 1:10 dilution and results were corrected for the dilution factor.

<sup>3</sup>Two replicates positive and reported as the mean of the two and one replicate detected below the limit of quantitation.

ND = Not Detected; RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking
**HCV RNA AccuSpan™ Linearity Panel**

2410-0166 (PHW805) / Batch # 10220359

---

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

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Expected Values (log IU/mL)</th>
<th>Observed Values on Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Version 2.0 (log IU/mL)</th>
<th>% Difference²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>4.70</td>
<td>4.12</td>
<td>-12.27</td>
</tr>
<tr>
<td>Sample 2</td>
<td>4.00</td>
<td>3.58</td>
<td>-10.56</td>
</tr>
<tr>
<td>Sample 3</td>
<td>3.70</td>
<td>3.28</td>
<td>-11.37</td>
</tr>
<tr>
<td>Sample 4</td>
<td>3.00</td>
<td>2.64</td>
<td>-11.95</td>
</tr>
</tbody>
</table>

**Test Date**

23-Sep-16

**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.**

X00055

**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](http://www.seracare.com)

A printed copy of the package insert or data sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com) or by phone at 508.244.6400