

# AccuSet™ HCV Mixed Titer Performance Panel

0810-0346 / Batch #10684955

## OVERVIEW

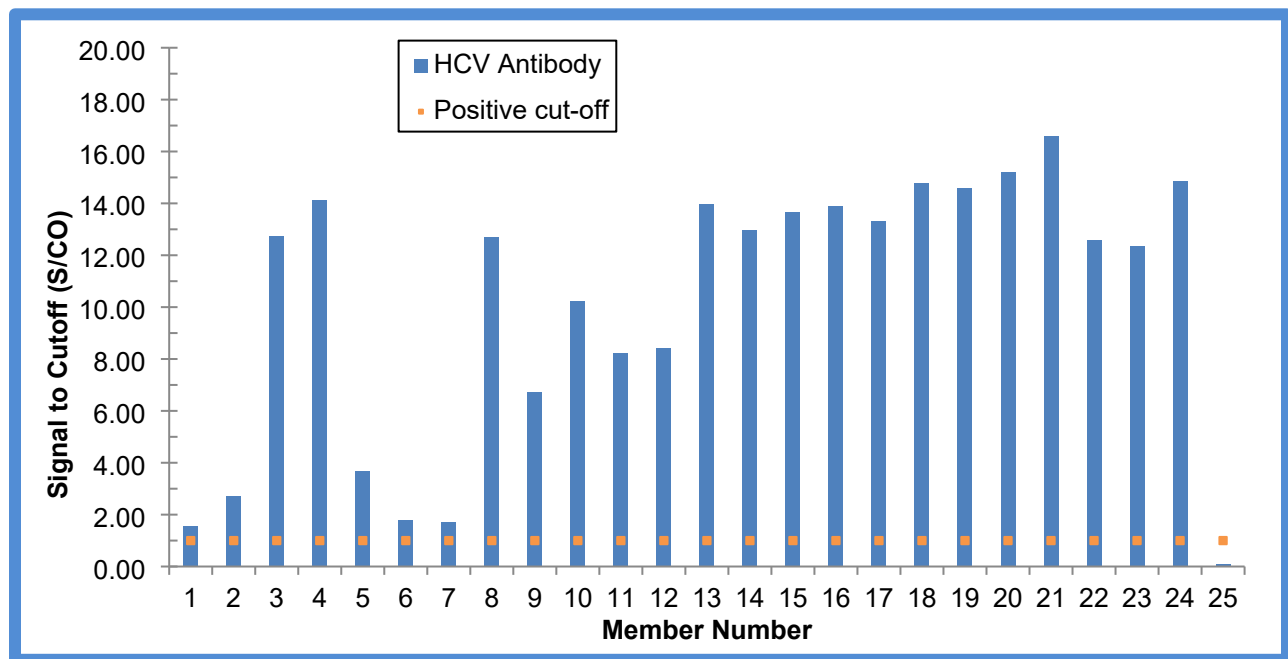
AccuSet™ HCV Mixed Titer Performance Panel, 0810-0346 / Batch #10684955 is a 25-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HCV. Each sample represents a single collection event. No preservatives were added.

Test results from commercially available HCV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity for anti-HCV test methods. Additional tests performed on HCV RNA and HCV antigen test methods are also provided. One sample is included as a non-reactive sample and is negative for all HCV test methods performed.

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: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for anti-HCV; all were found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

AccuSet™ HCV Mixed Titer Performance Panel



This graph demonstrates reactivity amongst panel members from the Abbott ARCHITECT (Anti-HCV) test method.

AccuSet<sup>™</sup> HCV  
 Mixed Titer Performance Panel  
 0810-0346 / Batch #10684955

**Panel Member Information**

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9239270	BD110230	07-Dec-1999
02	9242322	BD110051	21-Aug-2009
03	10395929	BD397206	08-Nov-2018
04	10418772	BD406221	26-Oct-2018
05	9239342	BD110245	11-May-2000
06	BM217432	BD104227	23-Mar-2007
07	9242333	BD110057	20-Aug-2009
08	10401950	BD398599	22-Oct-2018
09	9115914	BD110548	09-Nov-1999
10	10418777	BD406224	28-Mar-2019
11	9239331	BD110261	11-Oct-1999
12	9115992	BD110589	25-May-2000
13	10401949	BD398603	05-Dec-2018
14	9218803	BD105326	06-Aug-2007
15	10418774	BD406222	04-Dec-2018
16	BM217319	BD103865	12-Dec-2006
17	9251941	BD110870	19-Feb-2011
18	9239335	BD110253	06-Jun-2000
19	9218688	BD105306	02-Aug-2007
20	9146123	BD110788	15-Oct-2002
21	9239343	BD110246	06-May-2000
22	10395930	BD397206	13-Nov-2018
23	10401951	BD398599	26-Oct-2018
24	9242978	BD110069	25-Nov-2009
25	10325214	BD357640	06-Feb-2014

# AccuSet™ HCV

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### HCV RNA<sup>1</sup>

Panel Member	Roche cobas® 6800/8800 HCV RNA (IU/mL)	Abbott Alinity m HCV RNA (IU/mL)
01	<b>&lt;15.00, TND*</b>	<b>&lt;LLOQ</b>
02	TND	TND
03	<b>2.52 x 10<sup>4</sup></b>	<b>2.80 x 10<sup>4</sup></b>
04	TND	<b>&lt;LLOQ, TND*</b>
05	TND	TND
06	TND	TND
07	TND	TND
08	<b>3.48 x 10<sup>4</sup></b>	<b>3.58 x 10<sup>4</sup></b>
09	TND	<b>&lt;LLOQ, TND*</b>
10	<b>1.33 x 10<sup>5</sup></b>	<b>1.16 x 10<sup>5</sup></b>
11	TND	TND
12	TND	TND
13	<b>7.62 x 10<sup>3</sup></b>	<b>9.12 x 10<sup>3</sup></b>
14	<b>4.74 x 10<sup>5</sup></b>	<b>2.90 x 10<sup>5</sup></b>
15	<b>4.43 x 10<sup>5</sup></b>	<b>3.91 x 10<sup>5</sup></b>
16	<b>&lt;15.00</b>	<b>1.55 x 10<sup>1</sup></b>
17	<b>7.08 x 10<sup>4</sup></b>	<b>5.46 x 10<sup>4</sup></b>
18	<b>2.96 x 10<sup>2</sup></b>	<b>9.60 x 10<sup>2</sup></b>
19	<b>&lt;15.00, TND*</b>	<b>&lt;LLOQ, TND*</b>
20	<b>3.04 x 10<sup>4</sup></b>	<b>3.03 x 10<sup>4</sup></b>
21	<b>&lt;15.00</b>	<b>4.60 x 10<sup>1</sup></b>
22	<b>3.56 x 10<sup>3</sup></b>	<b>3.90 x 10<sup>3</sup></b>
23	<b>5.09 x 10<sup>4</sup></b>	<b>6.31 x 10<sup>4</sup></b>
24	<b>1.15 x 10<sup>2</sup></b>	<b>1.34 x 10<sup>2</sup></b>
25	TND	TND
Test Date	08-Nov-2023, 13-Nov-2023	08-Nov-2023
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	NA	389099
Kit Exp. Date	NA	30-Dec-2024

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

\*Interpretation variability; individual replicates reported.

TND = Target Not Detected; LLOQ = Lower Limit of Quantitation; RL = Reference Lab; NA = Not Available

# AccuSet™ HCV

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### HCV Antibody and HCV Antigen<sup>1</sup>

Panel Member	Abbott ARCHITECT Anti-HCV (S/CO)	Abbott Alinity s Anti-HCV (S/CO)	Roche cobas® Elecsys Anti-HCV II (COI)	Abbott ARCHITECT HCV Ag (fmol/L)
01	<b>1.56</b>	0.90	<b>188.50</b>	0.00
02	<b>2.73</b>	<b>2.71</b>	<b>46.83</b>	0.00
03	<b>12.75</b>	<b>9.48</b>	<b>122.95</b>	<b>121.10</b>
04	<b>14.12</b>	<b>10.43</b>	<b>79.60</b>	0.00
05	<b>3.69</b>	<b>2.46</b>	<b>110.85</b>	0.00
06	<b>1.80</b>	<b>1.25</b>	0.08	0.00
07	<b>1.72</b>	<b>1.67</b>	<b>37.71</b>	0.00
08	<b>12.70</b>	<b>9.16</b>	<b>93.81</b>	<b>481.44</b>
09	<b>6.73</b>	<b>4.19</b>	<b>213.95</b>	0.00
10	<b>10.23</b>	<b>7.47</b>	<b>207.45</b>	<b>1987.58</b>
11	<b>8.24</b>	<b>5.55</b>	<b>227.50</b>	0.00
12	<b>8.44</b>	<b>5.31</b>	<b>136.55</b>	0.00
13	<b>13.98</b>	<b>9.35</b>	<b>89.71</b>	<b>28.15</b>
14	<b>12.99</b>	<b>8.39</b>	<b>102.18</b>	<b>1829.05</b>
15	<b>13.66</b>	<b>9.64</b>	<b>15.05</b>	<b>989.63</b>
16	<b>13.88</b>	<b>9.94</b>	<b>71.58</b>	<b>7.45</b>
17	<b>13.31</b>	<b>9.65</b>	<b>93.14</b>	<b>532.23</b>
18	<b>14.78</b>	<b>10.17</b>	<b>72.75</b>	<b>438.50</b>
19	<b>14.58</b>	<b>10.19</b>	<b>91.72</b>	0.00
20	<b>15.22</b>	<b>11.71</b>	<b>47.93</b>	<b>92.72</b>
21	<b>16.58</b>	<b>12.20</b>	<b>14.87</b>	1.60
22	<b>12.57</b>	<b>9.01</b>	<b>127.40</b>	<b>30.11</b>
23	<b>12.35</b>	<b>9.12</b>	<b>93.94</b>	<b>348.60</b>
24	<b>14.88</b>	<b>10.02</b>	<b>70.39</b>	1.72
25	0.08	0.06	0.09	0.00
Test Date	03-Nov-2023	10-Nov-2023	20-Nov-2023	15-Nov-2023
Test Site	LGC	RL	RL	RL
Kit Part Code	1L79	NA	NA	NA
Kit Lot No.	56375BE00	52135BE00, 52466BE00	NA	54301LP77
Kit Exp. Date	28-Jul-2024	18-Apr-2024, 27-Apr-2024	NA	09-May-2024

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.  
LGC = LGC Clinical Diagnostics; RL = Reference Lab; NA = Not Available

# AccuSet™ HCV

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### HCV Confirmatory Assay<sup>1</sup>

#### INNOGENETICS® INNO-LIA™ HCV Score

#### Band Results

Panel Member	HCV Antibody Interpretation	C1	C2	E2	NS3	NS4	NS5
01	<b>POS</b>	-	1+	-	<u>±</u>	-	-
02	<b>POS</b>	2+	2+	-	2+	-	-
03	<b>POS</b>	-	1+	-	3+	2+	2+
04	<b>POS</b>	3+	2+	2+	4+	4+	3+
05	<b>POS</b>	2+	1+	<u>±</u>	2+	1+	-
06	IND	-	-	-	1+	-	-
07	<b>POS</b>	2+	1+	1+	1+	2+	-
08	<b>POS</b>	-	-	-	3+	2+	-
09	<b>POS</b>	-	-	-	3+	1+	-
10	IND	-	-	-	3+	-	-
11	<b>POS</b>	2+	2+	-	3+	1+	-
12	<b>POS</b>	1+	-	-	2+	2+	-
13	<b>POS</b>	-	-	-	4+	3+	-
14	<b>POS</b>	4+	3+	-	3+	-	-
15	<b>POS</b>	4+	2+	<u>±</u>	4+	4+	4+
16	<b>POS</b>	-	-	-	4+	2+	-
17	<b>POS</b>	4+	3+	3+	4+	4+	2+
18	<b>POS</b>	2+	2+	3+	4+	-	-
19	<b>POS</b>	3+	2+	-	4+	3+	-
20	<b>POS</b>	4+	3+	2+	4+	4+	-
21	<b>POS</b>	4+	4+	2+	4+	4+	3+
22	<b>POS</b>	-	2+	-	3+	2+	1+
23	<b>POS</b>	-	-	-	4+	1+	-
24	<b>POS</b>	4+	1+	-	4+	4+	-
25	NEG	-	-	-	-	-	-

Test Date 22-Nov-2023

Test Site RL

Kit Part Code NA

Kit Lot No. 411025

Kit Exp. Date 30-Jun-2024

<sup>1</sup>Results are reported as singlicate testing; positive/reactive results are noted in bold red.

RL = Reference Lab; NA = Not Available

NEG = Negative; POS = Positive; IND = Indeterminate

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 [CDx-Info@LGCGroup.com](mailto:CDx-Info@LGCGroup.com) or by phone at 508.244.6400.