

# AccuSet™ HCV Verification Panel 1

0810-0325 / Batch #10670480

## OVERVIEW

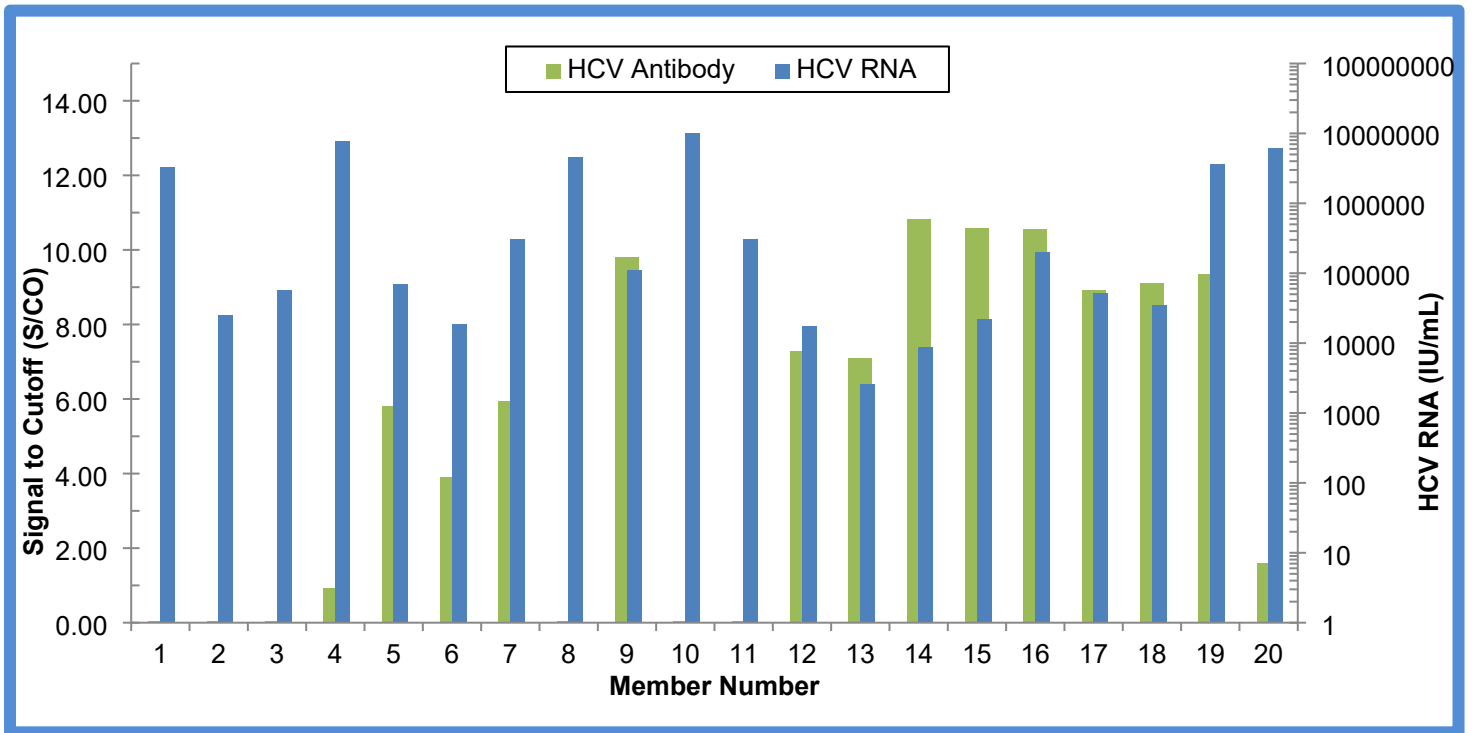
AccuSet™ HCV Verification Panel 1, 0810-0325 / Batch #10670480, is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.5 mL per vial). Panel members represent bleeds from multiple individuals positive for HCV. Each sample represents a single collection 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 HCV RNA and anti-HCV reactivity.

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 HCV; all were found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates reactivity amongst panel members from the Roche cobas® (HCV RNA) and Abbott Alinity s (Anti-HCV) test methods.

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## Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9232114	NA	13-Jun-2008
02	9232130	NA	21-Jul-2008
03	9242374	0451067043	21-Jul-2009
04	9106297	LU007348	29-Jan-2000
05	10456790	19500611255	04-Jul-2019
06	10456791	19500609884	02-Jul-2019
07	10456792	14902042021	30-Jul-2019
08	10329400	01206024564	04-Dec-2017
09	9148706	27046427	24-Jan-2003
10	10354471	14401702618	05-Apr-2018
11	9216276	0090822700	30-Jun-2007
12	10395933	62709629791	04-Dec-2018
13	10395934	62709953903	06-Dec-2018
14	9154306	NA	NA
15	9154307	NA	NA
16	9230521	0608A063	NA
17	10430536	21100117840	01-Nov-2018
18	10430538	21100110550	28-Oct-2018
19	10440668	18900800018	16-Apr-2019
20	9106298	LU007365	01-Feb-2000

NA = Not Available

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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>3.28E+06</b>	<b>3.19E+06</b>
02	<b>2.52E+04</b>	<b>3.08E+04</b>
03	<b>5.72E+04</b>	<b>7.59E+04</b>
04	<b>7.68E+06</b>	<b>6.70E+06</b>
05	<b>6.93E+04</b>	<b>8.27E+04</b>
06	<b>1.85E+04</b>	<b>2.09E+04</b>
07	<b>3.09E+05</b>	<b>3.50E+05</b>
08	<b>4.63E+06</b>	<b>4.65E+06</b>
09	<b>1.10E+05</b>	<b>1.03E+05</b>
10	<b>1.01E+07</b>	<b>9.83E+06</b>
11	<b>3.11E+05</b>	<b>2.99E+05</b>
12	<b>1.77E+04</b>	<b>2.07E+04</b>
13	<b>2.59E+03</b>	<b>2.40E+03</b>
14	<b>8.77E+03</b>	<b>9.06E+03</b>
15	<b>2.20E+04</b>	<b>2.41E+04</b>
16	<b>2.01E+05</b>	<b>1.71E+05</b>
17	<b>5.13E+04</b>	<b>4.66E+04</b>
18	<b>3.47E+04</b>	<b>3.21E+04</b>
19	<b>3.63E+06</b>	<b>3.43E+06</b>
20	<b>6.05E+06</b>	<b>7.46E+06</b>
Test Date	07-Jul-2023	10-Jul-2023
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	NA	385356
Kit Exp. Date	NA	10-Feb-2025

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

# AccuSet™ HCV Verification Panel 1

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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	0.07	0.03	0.06	<b>1.03E+04</b>
02	0.09	0.04	0.07	<b>2.81E+03</b>
03	0.05	0.03	0.06	<b>5.20E+02</b>
04	<b>2.55</b>	0.85, <b>1.00*</b>	<b>1.32</b>	<b>1.30E+04</b>
05	<b>7.57</b>	<b>5.80</b>	<b>184.15</b>	<b>1.07E+02</b>
06	<b>4.85</b>	<b>3.90</b>	<b>138.20</b>	<b>3.65E+01</b>
07	<b>8.44</b>	<b>5.93</b>	<b>126.80</b>	<b>5.86E+02</b>
08	0.07	0.04	0.08	<b>4.36E+03</b>
09	<b>15.17</b>	<b>9.80</b>	<b>21.06</b>	<b>1.20E+03</b>
10	0.09	0.05	0.07	<b>&gt;2.00E+04</b>
11	0.06	0.03	0.08	<b>1.09E+03</b>
12	<b>10.09</b>	<b>7.29</b>	<b>152.55</b>	<b>1.69E+01</b>
13	<b>9.55</b>	<b>7.10</b>	<b>147.85</b>	1.18E+00
14	<b>16.33</b>	<b>10.82</b>	<b>19.62</b>	<b>1.86E+03</b>
15	<b>16.19</b>	<b>10.57</b>	<b>21.26</b>	<b>8.06E+02</b>
16	<b>14.02</b>	<b>10.55</b>	<b>87.51</b>	<b>1.06E+03</b>
17	<b>13.39</b>	<b>8.92</b>	<b>32.56</b>	<b>3.08E+01</b>
18	<b>13.42</b>	<b>9.10</b>	<b>19.66</b>	<b>4.54E+01</b>
19	<b>11.32</b>	<b>9.36</b>	<b>121.50</b>	<b>3.30E+03</b>
20	<b>3.28</b>	<b>1.59</b>	<b>34.34</b>	<b>1.09E+04</b>
Test Date	05-Jul-2023	07-Jul-2023	01-Aug-2023	19-Jul-2023
Test Site	LGC	RL	RL	RL
Kit Part Code	1L79	NA	NA	NA
Kit Lot No.	47588BE00	50274BE00	NA	51301LP76
Kit Exp. Date	15-Nov-2023	09-Feb-2024	NA	02-Mar-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.

RL = Reference Lab; LGC = LGC Clinical Diagnostics; NA = Not Available

# AccuSet™ HCV

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### HCV Confirmatory Assay

#### INNOGENETICS® INNO-LIA™ HCV Score<sup>1</sup>

#### Band Results

Panel Member	HCV Antibody Interpretation	C1	C2	E2	NS3	NS4	NS5
01	NEG	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-
04	<b>POS</b>	1+	±	-	-	-	-
05	<b>POS</b>	-	-	-	2+	2+	-
06	<b>POS</b>	-	-	-	2+	2+	-
07	IND	-	-	-	2+	-	-
08	NEG	-	-	-	-	-	-
09	<b>POS</b>	2+	2+	1+	4+	4+	4+
10	NEG	-	-	-	-	-	-
11	NEG	-	-	-	-	-	-
12	<b>POS</b>	1+	-	-	2+	-	-
13	<b>POS</b>	±	-	-	2+	-	-
14	<b>POS</b>	4+	2+	-	4+	4+	4+
15	<b>POS</b>	4+	2+	-	4+	4+	4+
16	<b>POS</b>	3+	1+	-	4+	-	2+
17	<b>POS</b>	-	1+	1+	4+	4+	2+
18	<b>POS</b>	-	2+	1+	4+	4+	2+
19	<b>POS</b>	3+	3+	-	2+	-	-
20	<b>POS</b>	2+	±	-	±	-	-
Test Date	19-Jul-2023						
Test Site	RL						
Kit Part Code	NA						
Kit Lot No.	410791						
Kit Exp. Date	30-Apr-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.