AccuSet™ HCV Worldwide Performance Panel

0810-0230 / Batch #10395789

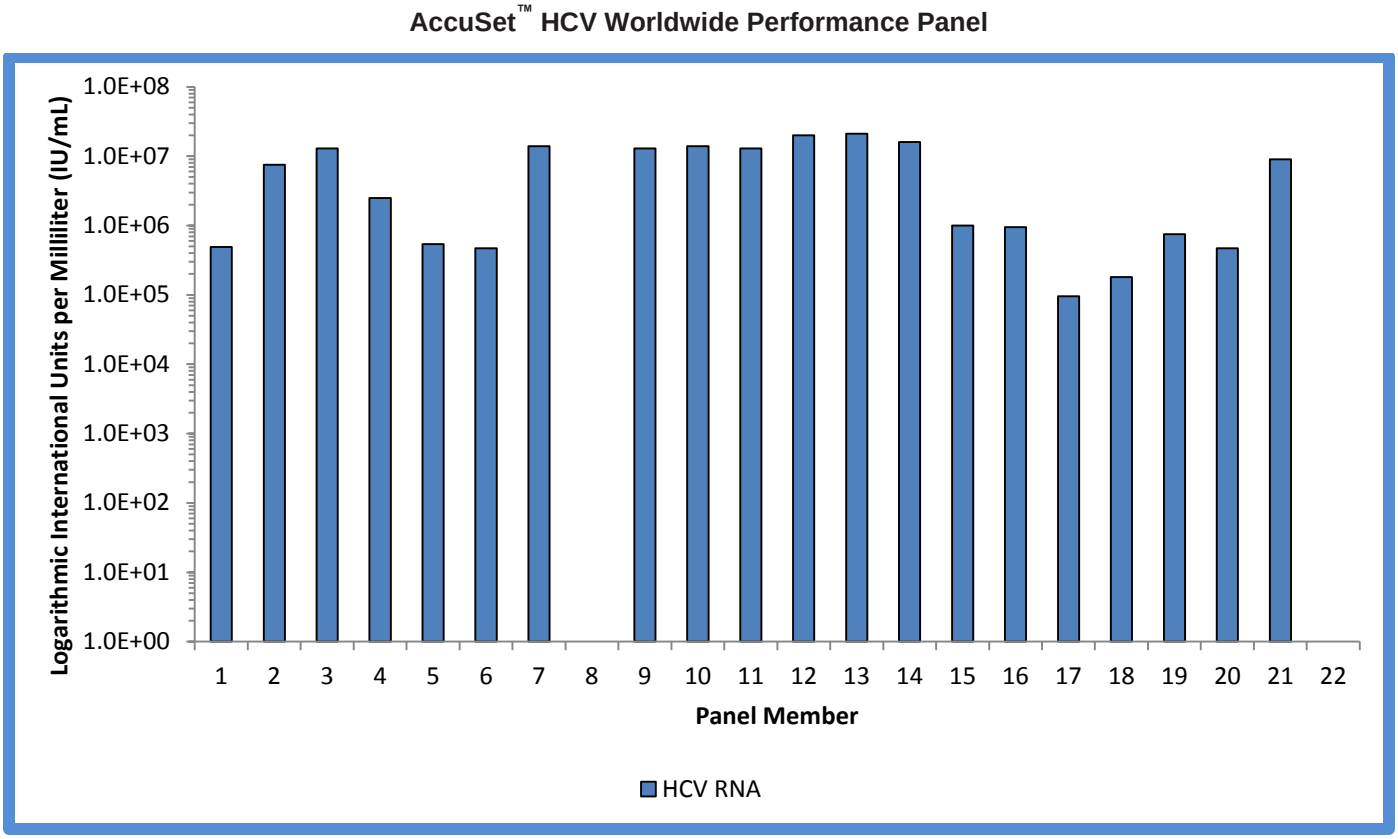
OVERVIEW

AccuSet™ HCV Worldwide Performance Panel 0810-0230 / Batch #10395789 is a 22-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from individuals positive for HCV genotypes 1 – 6 with varying subtypes. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available, research use only, and laboratory developed tests for hepatitis C are included for characterization of panel members. This panel of human plasma samples demonstrates a range of HCV viral load and antibody reactivities to several molecular and serological HCV test methods. Two members are included as non-reactive samples and are negative for all HCV test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.



This graph demonstrates HCV RNA reactivity amongst panel members utilizing test results from the Roche cobas 6800 HCV RNA assay.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Country Of Origin	Anticoagulant
01	9229698	BD106546	02-Apr-2008	United States	4% Sodium Citrate
02	10329400	BD360827	04-Dec-2017	United States	4% Sodium Citrate
03	10329408	BD360834	11-Dec-2017	United States	4% Sodium Citrate
04	9115982	BD110586	NA	NA	4% Sodium Citrate
05	9148706	BD110832	24-Jan-2003	NA	4% Sodium Citrate
06	BM216846	BD103217	26-Jun-2006	United States	4% Sodium Citrate
07	10354474	BD375494	24-Feb-2018	NA	4% Sodium Citrate
08	10370035	BD384862	15-Nov-2014	United States	4% Sodium Citrate
09	10354477	BD375496	13-Apr-2018	NA	4% Sodium Citrate
10	9255089	BD111153	12-Sep-2011	United States	4% Sodium Citrate
11	10354475	BD375494	26-Feb-2018	NA	4% Sodium Citrate
12	10339080	BD365260	4-Feb-2018	United States	4% Sodium Citrate
13	10339087	BD365264	27-Feb-2018	United States	4% Sodium Citrate
14	10354471	BD375492	05-Apr-2018	NA	4% Sodium Citrate
15	9216276	BD104971	30-Jun-2007	NA	4% Sodium Citrate
16	9223348	BD106010	25-Jan-2008	NA	NA
17	9219513	BD105431	24-Sep-2007	NA	NA
18	10375714	NA	03-Aug-2017	Spain	CPD
19	10375715	NA	20-Nov-2016	Spain	CPD
20	10283300	BD336081	28-Jul-2017	Belgium	4% Sodium Citrate
21	9262137	BD111417	30-Aug-2012	NA	CPD
22	10370168	BD384994	30-Dec-2014	United States	4% Sodium Citrate

NA = Not Available

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HCV Genotype and HCV RNA

Panel Member	GenMark Dx eSensor HCVg Direct Test	Siemens HCV Genotyping by NS5B Sequencing	Siemens Versant HCV Genotype 2.0 Assay	Abbott m2000 Real*time* HCV RNA (IU/mL)[1,2]	Roche cobas 6800 HCV RNA (IU/mL)[1,2]
01	**1A**	**1A**	**1A**	**2.8E+05**	**4.9E+05**
02	**1A**	**1A**	**1A**	**3.8E+06**	**7.5E+06**
03	**1A**	**1A**	**1A**	**8.7E+06**	**1.3E+07**
04	**1A**	**1A**	**1A**	**1.3E+06**	**2.5E+06**
05	**1A**	**1A**	**1A**	**2.5E+05**	**5.4E+05**
06	**1B**	**1B**	**1B**	**1.8E+05**	**4.7E+05**
07	**2B**	**2B**	**2B**	**7.8E+06**	**1.4E+07**
08	NT	NT	NT	TND	TND
09	**2A/2C**	**2A**	**2B**	**5.8E+06**	**1.3E+07**
10	**2B**	**2B**	**2B**	**6.6E+06**	**1.4E+07**
11	**2B**	**2B**	**2B**	**7.4E+06**	**1.3E+07**
12	**3**	**3A**	**3A**	**1.0E+07**	**2.0E+07**
13	**3**	**3A**	**3A**	**1.1E+07**	**2.1E+07**
14	**3**	**3A**	**3A**	**7.0E+06**	**1.6E+07**
15	**3**	**3A**	**3A**	**5.3E+05**	**1.0E+06**
16	**3**	**3A**	**3A**	**5.9E+05**	**9.5E+05**
17	**4**	**4A**	**4ACD**	**7.6E+04**	**9.6E+04**
18	**4**	**4**	**4ACD**	**1.2E+05**	**1.8E+05**
19	**4**	**4D**	**4ACD**	**6.7E+05**	**7.5E+05**
20	**5**	**5A**	**5A**	**1.2E+05**	**4.7E+05**
21	**6**	**6**	**6**	**2.9E+06**	**9.0E+06**
22	NT	NT	NT	TND	TND
Test Date	07-Feb-2019	08-Feb-2019	08-Feb-2019	08-Feb-2019	06-Feb-2019
Test Site	RL	RL	RL	RL	RL
Kit Part Code	NA	NA	NA	NA	NA
Kit Lot No.	53167894	NA	NA	NA	NA
Kit Exp. Date	20-Jul-2019	NA	NA	NA	NA
Kit Regulatory Status	RUO	LDT	RUO	IVD	IVD/CE

[1]Results are reported as International Units per mL (IU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as the mean result of duplicate testing.
NA = Not Available; NT = Not Tested; TND = Target Not Detected
RL = Reference Lab
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research Use Only; LDT = Laboratory Developed Test

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HCV Antigen and Anti-HCV

Panel Member	Abbott ARCHITECT HCV Ag (TV)[1,3]	Abbott ARCHITECT Anti-HCV (s/co)[2,3]	Abbott PRISM Anti-HCV (s/co)[2,3]	Ortho HCV Version 3.0 ELISA Test System (s/co)[2,3]
01	**3762.0**	0.5	0.2	0.1
02	**9793.1**	0.2	0.1	0.0
03	**13663.1**	0.0	0.1	0.0
04	**2678.1**	**17.4**	**5.2**	**>6.5**
05	**1982.3**	**15.5**	**5.4**	**>6.5**
06	**658.9**	**13.0**	**3.8**	**>6.5**
07	**>20000**	0.1	0.1	0.0
08	0.2	0.2	0.1	0.0
09	**>20000**	0.2	0.1	0.0
10	**>20000**	0.1	0.1	0.0
11	**13013.5**	0.1	0.1	0.0
12	**14495.9**	0.1	0.2	0.0
13	**8187.5**	0.0	0.1	0.0
14	**>20000**	0.1	0.1	0.0
15	**1128.2**	0.1	0.1	0.0
16	**3902.2**	0.0	0.2	0.0
17	**345.1**	0.1	0.1	0.0
18	**508.6**	**12.1**	**4.8**	**>6.5**
19	**1551.4**	**12.3**	**4.1**	**>6.5**
20	**81.0**	**14.2**	**4.1**	**>6.5**
21	**11369.9**	**13.7**	**3.3**	**>6.5**
22	0.0	0.8	0.2	0.0
Test Date	25-Feb-2019	05-Feb-2019	05-Feb-2019	04-Feb-2019
Test Site	RL	SC	RL	SC
Kit Part Code	NA	1L79	NA	930740
Kit Lot No.	95301LP52	90330LI00	NA	TXE672
Kit Exp. Date	11-Oct-2019	02-Jun-2019	NA	12-Jul-2019
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE	IVD

[1]Results are reported as Test Value (TV); positive/reactive results are noted in bold red.
[2]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
NA = Not Available
RL = Reference Lab; SC = SeraCare
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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Anti-HCV

Panel Member	INNO-LIA HCV Score Band Pattern[1]	Result[1]
01	C2	IND
02	No Bands	NEG
03	No Bands	NEG
04	**C1, C2, E2, NS3, NS4, NS5**	**POS**
05	**C1, C2, E2, NS3, NS4, NS5**	**POS**
06	**C1, C2, E2, NS3, NS4**	**POS**
07	No Bands	NEG
08	No Bands	NEG
09	No Bands	NEG
10	No Bands	NEG
11	No Bands	NEG
12	No Bands	NEG
13	No Bands	NEG
14	No Bands	NEG
15	No Bands	NEG
16	No Bands	NEG
17	No Bands	NEG
18	**C1, C2, E2, NS3, NS4**	**POS**
19	**C1, C2, E2, NS3, NS4, NS5**	**POS**
20	**C1, C2, NS3, NS4, NS5**	**POS**
21	**C1, C2, E2, NS3**	**POS**
22	No Bands	NEG
Test Date	25-Feb-2019	
Test Site	RL	
Kit Part Code	NA	
Kit Lot No.	405623	
Kit Exp. Date	31-Oct-2019	
Kit Regulatory Status	IVD/CE	

[1] Positive/reactive results are noted in bold red.
POS = Positive; NEG = Negative; IND = Indeterminate
NA = Not Available
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.