

OVERVIEW

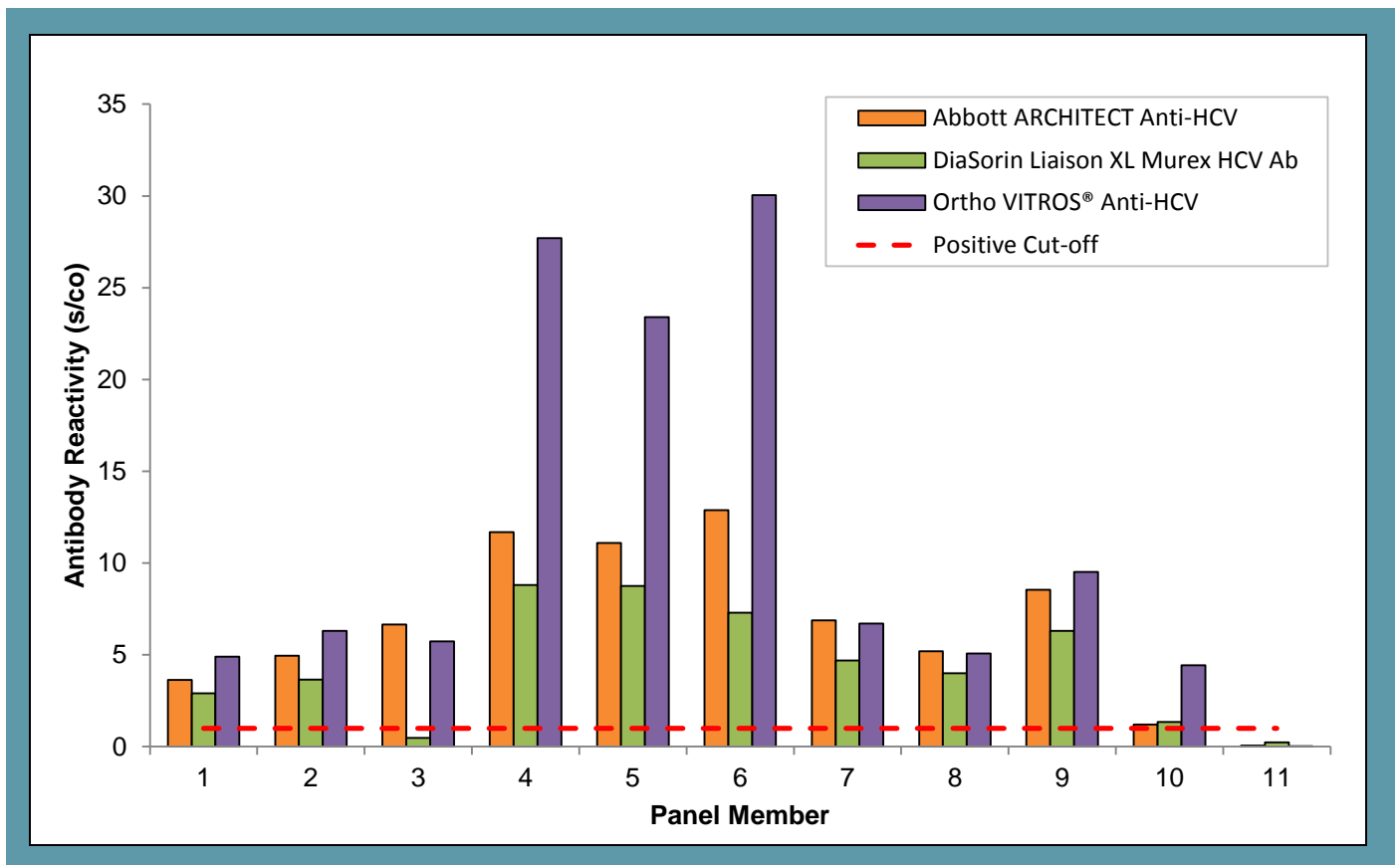
HCV Low Titer AccuSet™ Performance Panel (0810-0192) is an 11-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HCV. Each sample represents a single collection 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 which approach the sensitivity limits for several anti-HCV test methods. 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 provided 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.

HCV Low Titer AccuSet™ Performance Panel



This graph demonstrates HCV antibody reactivity amongst panel members utilizing test results from the Abbott ARCHITECT, DiaSorin Liaison XL Murex, and Ortho VITROS test methods.

HCV Low Titer AccuSet™ Performance Panel

0810-0192

DATA SHEET

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #
01	9115968	BD110581*
02	9115969	NA
03	9141010	NA
04	9243978	BD110090*
05	9239417	BD107565*
06	9233612	BD107035
07	9140907	NA
08	9140906	NA
09	9242974	BD110072*
10	9238999	BD107545*
11	10054053	NA

*Panel members 1, 4, 5, 9, and 10 were also utilized in SeraCare HCV Mixed Titer AccuSet™ Performance Panel (0810-0175).
NA = Not Available

HCV RNA and Antigen

Panel Member	Abbott Realtime HCV m2000 (IU/mL) ^{1,3}	Roche COBAS® Ampliprep/COBAS® Taqman® HCV Quantitative Test, v2.0 (IU/mL) ^{1,3}	Abbott ARCHITECT HCV Ag (fmol/L) ^{2,3}
01	Not Detected	Not Detected	0.00
02	Not Detected	Not Detected	0.00
03	Not Detected	Not Detected	0.00
04	836302	1125554	2821.61
05	875	1571	2.32
06	771142	1153591	2210.46
07	5458	6422	630.23
08	40988	41146	2657.96
09	204144	201030	4111.92
10	1298240	1193605	11475.60
11	Not Detected	Not Detected	0.00
Test Date	26-Apr-15	29-Mar-15	14-Apr-15
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	NA	NA	47161LP33
Kit Exp. Date	NA	NA	21-Sep-15
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE

¹Results are reported as international units per mL (IU/mL); positive/reactive results are noted in bold red.

²Results are reported as international units per femtomole per liter (fmol/L); positive/reactive results are noted in bold red.

³Results are reported as the mean result of duplicate testing.

RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking



HCV Low Titer AccuSet™ Performance Panel

0810-0192

DATA SHEET

HCV Antibody

Panel Member	Abbott ARCHITECT Anti-HCV (s/co) ^{1,2}	DiaSorin Liaison XL Murex HCV Ab (s/co) ^{1,2}	DiaSorin Murex anti- HCV (version 4.0) (s/co) ^{1,2}	Ortho HCV Version 3.0 ELISA (s/co) ^{1,2}
01	3.63	2.90	1.90	4.93*
02	4.95	3.65	3.39	4.93*
03	6.66	0.48	0.72	4.63
04	11.69	8.80	9.35	4.93*
05	11.10	8.75	7.94	4.93*
06	12.88	7.30	0.59	4.93*
07	6.87	4.70	7.00	4.93*
08	5.19	4.00	3.56	4.33
09	8.55	6.30	2.50	4.93*
10	1.20	1.35	6.37	2.12
11	0.06	0.24	0.53	0.01
Test Date	25-Mar-15	20-Apr-15	23-Apr-15	26-Mar-15
Test Site	SC	RL	RL	SC
Kit Part Code	1L79	NA	NA	930740
Kit Lot No.	47108LI00	NA	NA	TXE618
Kit Exp. Date	01-Nov-15	NA	NA	31-Jul-15
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE	IVD

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

*Results are off-scale.

SC = SeraCare; RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

HCV Low Titer AccuSet™ Performance Panel

0810-0192

DATA SHEET

HCV Antibody

Panel Member	Ortho VITROS® anti-HCV (s/co) ^{1,2}	Siemens ADVIA Centaur® HCV Ab (s/co) ^{1,2}	Fujirebio INNO-LIA® HCV Score	OraSure OraQuick® HCV Rapid Antibody Test
01	4.90	5.66	Positive	Non-Reactive
02	6.30	8.92	Positive	Non-Reactive
03	5.74	5.52	Negative	Non-Reactive
04	27.70	>11.00	Positive	Reactive
05	23.40	>11.00	Positive	Reactive
06	30.05	>11.00	Positive	Reactive
07	6.71	>11.00	Positive	Reactive
08	5.07	>11.00	Positive	Reactive
09	9.51	>11.00	Positive	Reactive
10	4.43	2.23	Positive	Non-Reactive
11	0.01	0.04	Negative	Non-Reactive
Test Date	01-Apr-15	01-Apr-15	15-Apr-15	26-Mar-15
Test Site	RL	RL	RL	SC
Kit Part Code	NA	NA	NA	1001-0181
Kit Lot No.	NA	NA	400920	6640796
Kit Exp. Date	NA	NA	31-Dec-15	31-Oct-15
Kit Regulatory Status	IVD	IVD	RUO	IVD/CE

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

SC = SeraCare; RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research Use Only

The Package Insert for this panel in PDF form 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

ASK ABOUT RELATED SERACARE PRODUCTS

- HCV AccuVert™ Seroconversion Panels
- HCV Disease State Biological Materials
- ACCURUN® independent quality controls
- SeraCon™ and Basematrix Processed Plasma

