

OVERVIEW

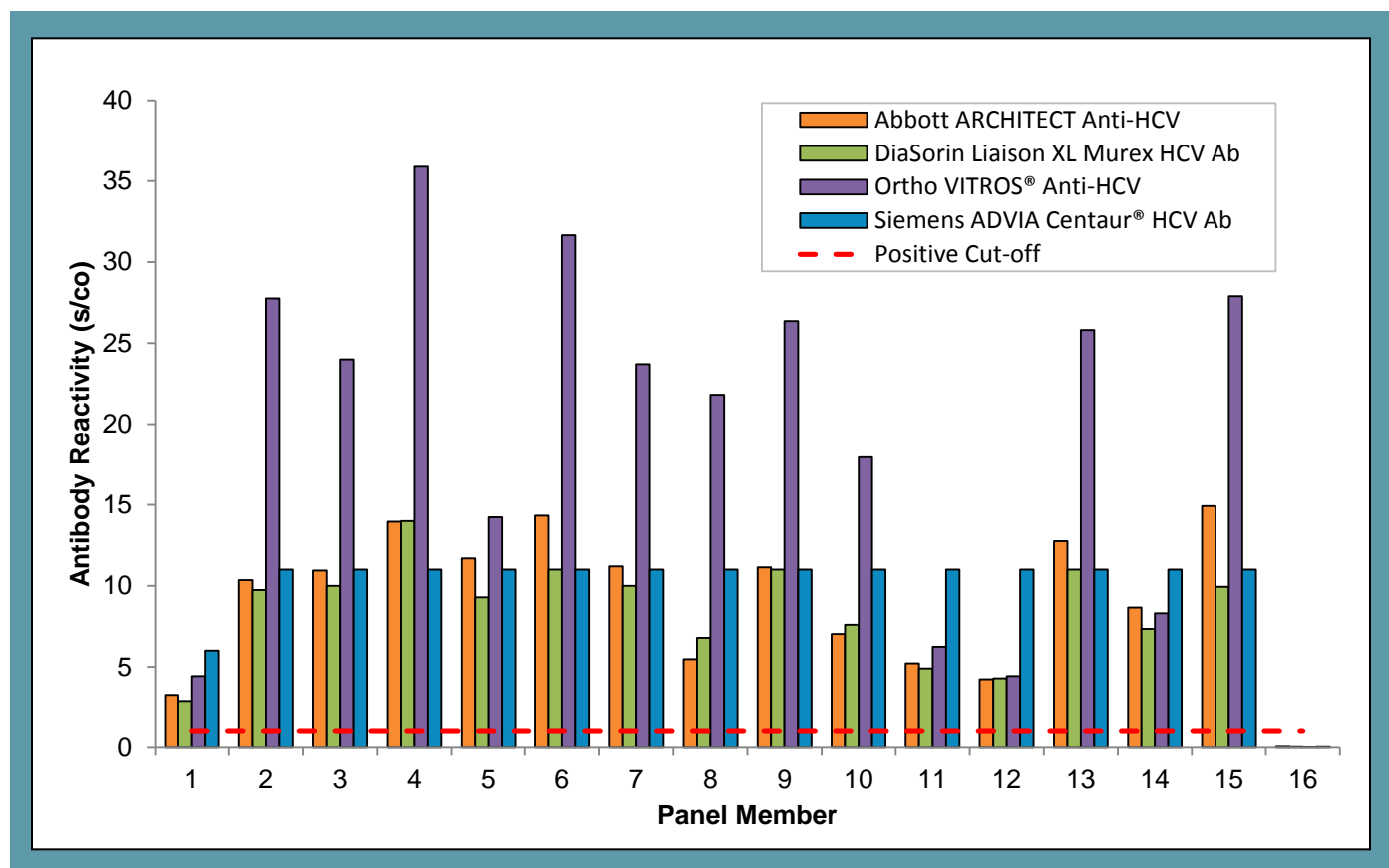
HCV Mixed Titer AccuSet™ Performance Panel (0810-0175) is a 16-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HCV. Each sample represents a single collection 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 for anti-HCV. 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 Mixed Titer AccuSet™ Performance Panel



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

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #
01	9115968	BD110581*
02	9243979	BD110090*
03	BM217428	BD104208
04	9233611	BD107034
05	9239430	BD107568
06	9235319	BD107293
07	9239418	BD107565*
08	9240632	BD110015
09	9218804	BD105326
10	9239001	BD107545*
11	9140907	NA
12	9140906	NA
13	9235316	BD107290
14	9242974	BD110072*
15	9249074	BD110374
16	10054053	BD210231

*Panel members 1, 2, 7, 10, and 14 were also utilized in SeraCare HCV Low Titer AccuSet™ Performance Panel (0810-0192).

NA = Not Available

HCV Mixed Titer AccuSet™ Performance Panel

0810-0175

DATA SHEET

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	12	Not Detected	0.00
02	6908555	8949282	16823.93
03	Not Detected	Not Detected	0.00
04	4759	7256	32.24
05	24602	25376	110.30
06	15185	21930	95.04
07	227721	233296	666.24
08	983055	1125653	2268.44
09	1716369	1884233	2756.35
10	2403607	2370496	5695.46
11	5567	6285	537.87
12	63006	60872	2614.68
13	716446	700716	2282.10
14	297204	267166	3664.26
15	5282820	6110651	8169.46
16	Not Detected	Not Detected	0.00
Test Date	12-Mar-15	13-Mar-15	17-Mar-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 Mixed Titer AccuSet™ Performance Panel

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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	3.27	2.90	1.85	1.88
02	10.36	9.75	9.96	>3.00
03	10.96	10.00	9.54	>3.00
04	13.97	14.00	10.56	>3.00
05	11.69	9.30	10.65	>3.00
06	14.34	11.00	12.38	>3.00
07	11.20	10.00	12.18	>3.00
08	5.47	6.80	3.10	>3.00
09	11.15	11.00	10.43	>3.00
10	7.03	7.60	5.12	>3.00
11	5.22	4.90	3.05	2.35
12	4.23	4.30	2.71	2.10
13	12.77	11.00	12.44	>3.00
14	8.67	7.35	2.52	>3.00
15	14.93	9.95	12.48	>3.00
16	0.06	0.03	0.58	0.01
Test Date	06-Mar-15	26-Mar-15	30-Mar-15	06-Mar-15
Test Site	SC	RL	RL	RL
Kit Part Code	1L79	NA	NA	NA
Kit Lot No.	43460LI00	NA	NA	NA
Kit Exp. Date	21-Jun-15	NA	NA	NA
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.

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HCV Mixed Titer AccuSet™ Performance Panel

0810-0175

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	4.42	6.01	Positive	Negative
02	27.75	11.00	Positive	Positive
03	24.00	11.00	Positive	Positive
04	35.90	11.00	Positive	Positive
05	14.25	11.00	Positive	Positive
06	31.65	11.00	Positive	Positive
07	23.70	11.00	Positive	Positive
08	21.80	11.00	Positive	Positive
09	26.35	11.00	Positive	Positive
10	17.95	11.00	Positive	Positive
11	6.25	11.00	Positive	Positive
12	4.42	11.00	Positive	Positive
13	25.80	11.00	Positive	Positive
14	8.31	11.00	Indeterminate	Positive
15	27.90	11.00	Positive	Positive
16	0.02	0.03	Negative	Negative
Test Date	07-Mar-15	20-Mar-15	01-Apr-15	06-Mar-15
Test Site	RL	RL	RL	SC
Kit Part Code	NA	NA	NA	1001-0181
Kit Lot No.	NA	NA	NA	6640796
Kit Exp. Date	NA	NA	NA	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.

³Results are reflective of concordant duplicate testing.

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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

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