

AccuSet™ SARS-CoV-2 Performance Panel

0820-0410 / (Batch #10497051)

OVERVIEW

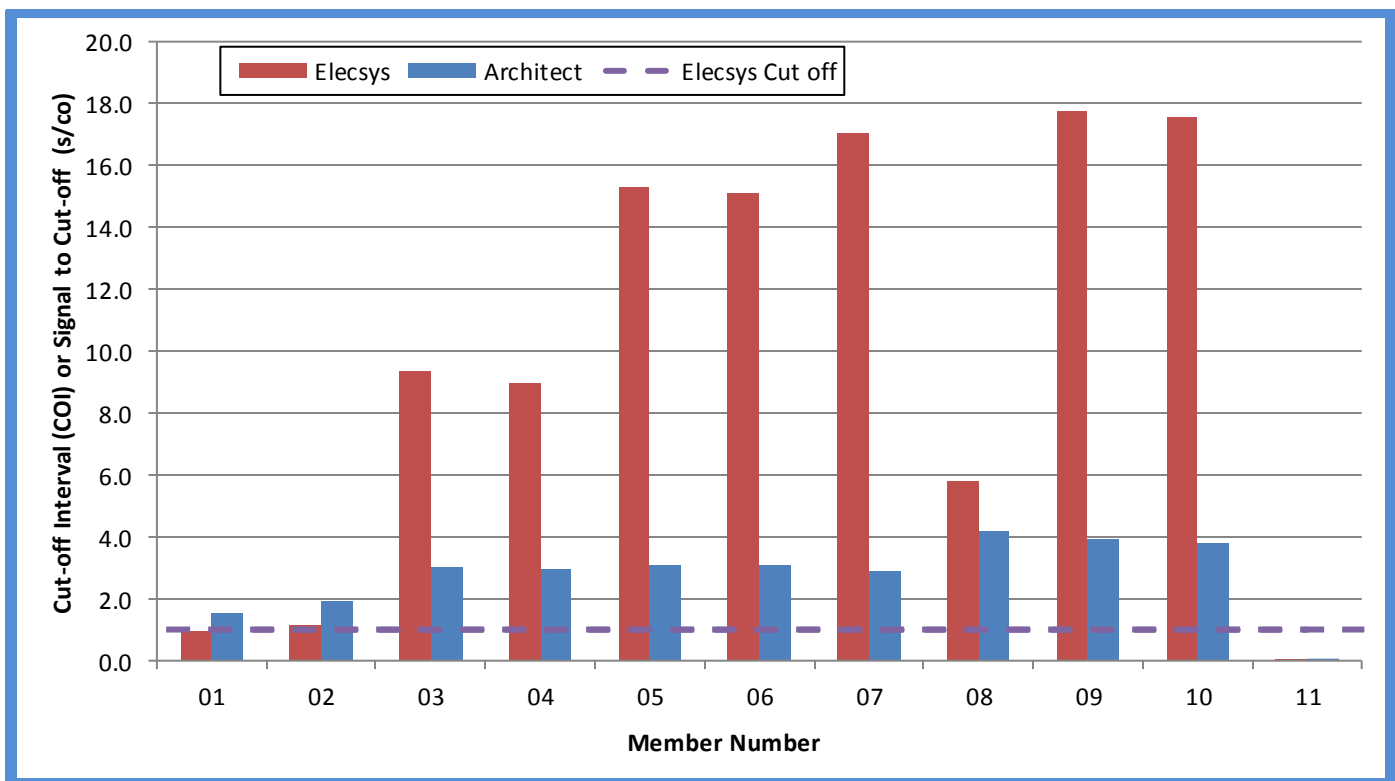
AccuSet™ SARS-CoV-2 Performance Panel (0820-0410 / Batch #10497051) is an 11-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent collections from multiple individuals positive for antibodies to SARS-CoV-2. Each member represents a single collection event. No preservatives were added.

Test results from commercially available SARS-CoV-2 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-SARS-CoV-2 test methods. One sample is included as a non-reactive sample and is negative for all SARS-CoV-2 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. Some panel members were found positive for SARS-CoV-2. The units that make up this panel were tested and found negative for anti-HIV-1/2, anti-HCV, and HBsAg. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates the comparison of results amongst panel members for the Abbott ARCHITECT SARS-CoV-2 IgG and Roche cobas® Elecsys® Anti-SARS-CoV-2 test methods.

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Panel Member Information¹

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Collection Date
01	10492248	BD433772	04/24/2020
02	10494770	BD436093	04/28/2020
03	10494762	BD436079	04/21/2020
04	10494763	BD436079	04/27/2020
05	10494764	BD436080	04/24/2020
06	10494765	BD436080	04/27/2020
07	10494949	BD436138	04/28/2020
08	10494950	BD436139	04/21/2020
09	10495104	BD436143	05/04/2020
10	10495105	BD436143	05/06/2020
11	10482351	BD340522	02/24/2020

¹Note: Donors of all positive members were previously tested and confirmed positive for SARS-CoV-2 virus using a molecular assay.

SARS CoV-2 Antibody

Panel Member	Abbott ARCHITECT SARS-CoV-2 IgG (s/co) ^{1,2}	Beckman Coulter DXL™ ACCESS SARS- CoV-2 IgG (s/co) ^{1,2}	Ortho VITROS® SARS CoV-2 IgG (s/co) ^{1,2}	Siemens ADVIA Centaur® SARS-CoV-2 IgG (COV2G) (s/co) ^{1,2,3}
01	1.56	2.76	4.32	1.12
02	1.96	3.45	5.08	2.32
03	3.01	2.57	5.37	1.99
04	2.96	2.49	5.12	2.03
05	3.10	0.83	1.88	0.48
06	3.07	0.83	1.68	0.48
07	2.91	1.24	3.41	1.29
08	4.19	23.77	12.05	>20.0⁴
09	3.92	2.41	4.19	2.05
10	3.79	2.47	3.90	2.11
11	0.03	0.04	0.01	0.00
Test Date	03-Jun-20	05-Aug-2020	05-Aug-20	04-Sep-2020, 08-Sep-2020 ³
Test Site	SC	RL	RL	RL
Kit Part Code	06R86	C58961	6199919	11206992
Kit Lot No.	15016M800	971193	110	004
Kit Exp. Date	11-Jul-2020	24-Dec-2020	05-Nov-2020	10-Mar-2021

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

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

³Results are reported as the mean result of samples run on two different days: one set run on 04-Sep-2020 and one set run on 08-Sep-2020.

⁴Result is off scale.

Test Site: SC = SeraCare; RL = Reference Lab

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SARS CoV-2 Antibody Total

Panel Member	Siemens ADVIA Centaur® SARS-CoV-2 Total (COV2T) (s/co) ^{1,2}	Siemens DIMENSION® EXL™ SARS-CoV-2 Total (CV2T) (COI) ^{2,3}	ROCHE cobas® Elecsys® Anti-SARS- CoV-2 (COI) ^{2,3}	Ortho VITROS® SARS- CoV-2-Total (CoV2T) (s/co) ^{1,2}
01	5.17	2443.5	0.96	37.2
02	3.28	1694.5	1.14	34.3
03	5.88	3728.0	9.38	119.5
04	5.25	3606.5	9.00	117.0
05	0.87	968.0	15.33	11.5
06	0.90	946.5	15.10	11.9
07	2.31	852.0	17.03	28.1
08	>10.0⁴	9219.0	5.79	147.5
09	>10.0⁴	8999.0	17.79	81.9
10	>10.0⁴	7581.5	17.59	79.9
11	< 0.05	62.0	0.07	0.1
Test Date	07-Aug-2020	07-Aug-2020	04-Jun-2020	05-Aug-2020
Test Site	RL	RL	RL	RL
Kit Part Code	11417412	11206710	NA	6199922
Kit Lot No.	035	EB0324	496298	23
Kit Exp. Date	22-Feb-2021	19-Nov-2020	30-Jun-2020	24-Nov-2020

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

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

³Results are reported as a cutoff index (COI); positive/reactive results are noted in bold red and negative results are in non-bold black.

⁴Result is off scale.

Test Site: RL = Reference Lab

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SARS-CoV-2 Antibody

Panel Member	EUROIMMUN Anti-SARS- CoV-2 IgA (s/co) ^{1,2}	EPITOPE DIAGNOSTICS COVID-19 IgM ELISA (s/co) ^{1,2}
01	2.15	0.53
02	1.45	0.47
03	5.77	0.67
04	5.34	0.52
05	2.14	0.76
06	2.08	0.54
07	1.46	0.50
08	10.08³	0.57
09	8.04	0.46
10	7.69	0.42
11	0.63	0.45
Test Date	04-Jun-20	04-Jun-20
Test Site	SC	SC
Kit Part Code	EI 2606-9601 A	KT-1033
Kit Lot No.	E200427BC	P791U
Kit Exp. Date	10/26/2020	04/30/2021

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

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

³Result is off scale.

Test Site: SC = SeraCare

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.