

AccuVert™ SARS-CoV-2 Seroconversion Panel

0820-0465 / (Batch #10544980)

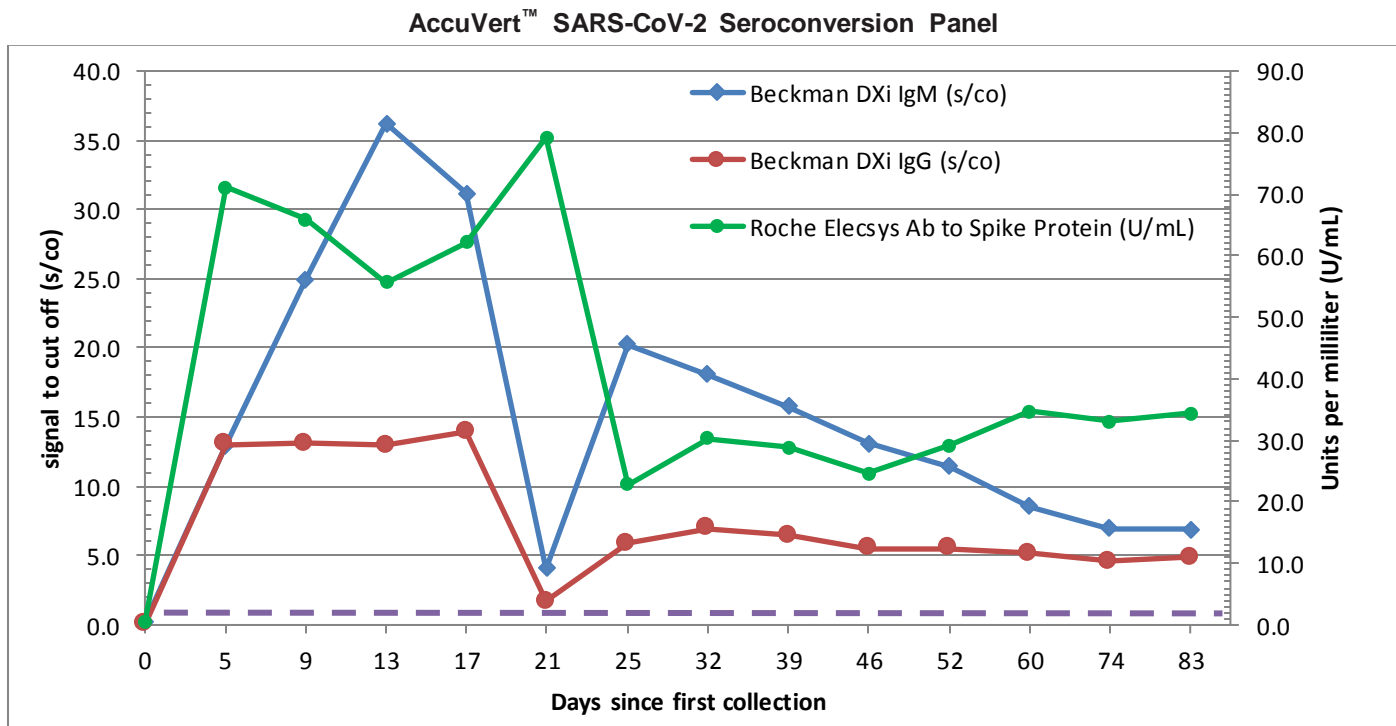
OVERVIEW

AccuVert™ SARS-CoV-2 Seroconversion Panel (0820-0465 / Batch #10544980) is a 14-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent serial collections received from a single individual over 83 days from October 30, 2020 to January 21, 2021 during the development of a SARS-CoV-2 infection and subsequent response. No preservatives were added.

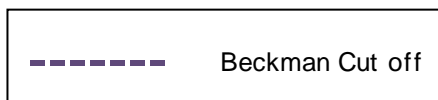
Test results from commercially available SARS-CoV-2 assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity for several anti-SARS-CoV-2 test methods. One sample is included as a non-reactive sample and is negative for 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. 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.



This graph demonstrates the comparison of results amongst panel members for the following test methods: Beckman DXi SARS-CoV-2 IgM, Beckman DXi SARS-CoV-2 IgG and Roche cobas® Elecsys® SARS-CoV-2 Antibody to SPIKE protein.



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Panel Member Information¹

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Collection Date	Days from initial collection	Donor symptoms at time of collection
01	10538089	BD459705	30-Oct-2020	0	Low-grade Fever of 99.8, Headache, Body Aches, Chills/Sweats, Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Sore Throat, Fatigue, Dizziness, Diarrhea, Abdominal Pain
02	10538090	BD459705	04-Nov-2020	5	Headache, Body Aches, Chills/Sweats, Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Sore Throat, Fatigue, Dizziness, Diarrhea, Abdominal Pain
03	10538091	BD459705	08-Nov-2020	9	Headache, Body Aches, Chills/Sweats, Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Sore Throat, Fatigue, Dizziness, Diarrhea, Abdominal Pain
04	10538092	BD459705	12-Nov-2020	13	Headache, Body Aches, Chills/Sweats, Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Sore Throat, Fatigue, Dizziness, Diarrhea, Abdominal Pain
05	10538093	BD459705	16-Nov-2020	17	Headache, Body Aches, Chills/Sweats, Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Sore Throat, Fatigue, Dizziness, Diarrhea, Abdominal Pain
06	10538094	BD459705	20-Nov-2020	21	Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Fatigue, intermittent Vertigo, Abdominal discomfort
07	10538095	BD459705	24-Nov-2020	25	Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Fatigue, intermittent Vertigo, Abdominal discomfort
08	10538096	BD459705	01-Dec-2020	32	Loss of taste/smell/appetite, Nasal Congestion, Chest Pressure, Shortness of Breath, Fatigue, intermittent Vertigo, Abdominal discomfort
09	10538097	BD459705	08-Dec-2020	39	Loss of taste/smell/appetite, Chest Pressure, Shortness of Breath, Fatigue, Abdominal discomfort
10	10538098	BD459705	15-Dec-2020	46	Loss of smell, Shortness of Breath, Fatigue
11	10538099	BD459705	21-Dec-2020	52	Loss of smell, Shortness of Breath, Fatigue
12	10538100	BD459705	29-Dec-2020	60	Fatigue
13	10538101	BD459705	12-Jan-2021	74	Fatigue
14	10538102	BD459705	21-Jan-2021	83	Fatigue

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

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SARS CoV-2 Antibody IgG

Panel Member	Beckman Coulter DXi 600™ 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) (INDEX) ^{2,3}
01	0.02	0.00	0.02
02	29.39	8.01	6.23
03	29.48	6.02	4.68
04	29.18	4.60	3.60
05	31.38	4.69	4.26
06	3.77	7.36	2.99
07	13.30	2.08	2.06
08	15.66	2.76	2.60
09	14.58	2.61	2.43
10	12.38	2.12	2.10
11	12.42	2.84	2.49
12	11.60	3.45	2.52
13	10.35	3.32	2.20
14	10.90	3.35	2.31
Test Date	31-Mar-2021	30-Mar-2021	30-Mar-2021
Test Site	RL	RL	RL
Kit Part Code	C58961	6199919	11206992
Kit Lot No.	124130	0350	007
Kit Exp. Date	30-Sep-2021	18-Jun-2021	04-Oct-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 INDEX; positive/reactive results are noted in bold red and negative results are in non-bold black.

RL = Reference Lab

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SARS CoV-2 Antibody Total

Panel Member	Siemens ADVIA Centaur® SARS-CoV-2 Total (COV2T) (INDEX) ^{1,5}	Siemens DIMENSION® EXL™ SARS-CoV-2 Total (CV2T) (QUAL units) ^{2,5}	ROCHE cobas® Elecsys® Anti-SARS-CoV-2 (COI) ^{3,5}	Ortho VITROS® SARS-CoV-2-Total (CoV2T)(s/co) ^{4,5}
01	<0.05	25	0.08	0.03
02	>10.0⁶	22,338	5.77	90.45
03	9.43	16,708	17.85	73.35
04	6.84	14,015	20.88	43.85
05	6.35	11,174	31.96	39.75
06	>10.0⁶	6,093	149.55	128.50
07	3.14	4,174	7.93	15.00
08	3.57	4,622	14.38	20.70
09	3.50	3,705	12.33	19.95
10	2.74	2,625	11.18	17.20
11	3.52	2,901	14.32	24.90
12	4.32	2,801	14.70	33.00
13	4.32	2,366	13.48	35.05
14	4.30	2,201	13.09	35.95
Test Date	30-Mar-2021	30-Mar-2021	30-Mar-2021	30-Mar-2021
Test Site	RL	RL	RL	RL
Kit Part Code	11206710	RF812	09203095190	619 9922
Kit Lot No.	010	EA1253	527896	0330
Kit Exp. Date	12-Oct-2021	10-Sep-2021	31-Mar-2021	30-Jul-2021

¹Results are reported as an INDEX; positive/reactive results are noted in bold red and negative results are in non-bold black.

²Results are reported as QUAL units; positive/reactive results are noted in bold red and negative results are in non-bold black.

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

⁴Results 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.

⁵Results are reported as the mean result of duplicate testing.

⁶Result is off scale.

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SARS-CoV-2 Antibody to SPIKE Protein and Antibody IgM

Panel Member	ROCHE cobas® Elecsys® ACVO2 S Ab to SPIKE PROTEIN (U/mL) ^{1,3}	Beckman Coulter DXi 600™ ACCESS SARS- CoV-2 IgM (s/co) ^{2,3}	Abbott Alinity i AdviseDx SARS- CoV-2 IgM (s/co) ^{2,3}	Abbott ARCHITECT SARS-CoV-2 IgM (s/co) ^{2,3}
01	<0.40	0.20	0.02	0.01
02	41.62	12.94	22.19	22.44
03	36.34	24.96	32.04	37.84
04	26.46	36.22	45.80	46.05
05	30.77	31.15	44.09	41.99
06	75.43	4.10	3.23	3.38
07	9.49	20.24	20.02	20.08
08	14.63	18.08	20.18	20.43
09	14.30	15.77	17.26	17.00
10	12.31	13.12	14.02	13.67
11	16.73	11.42	13.55	13.48
12	23.09	8.58	11.00	11.19
13	22.63	6.99	10.19	9.76
14	23.53	6.93	8.89	8.94
Test Date	30-Mar-2021	31-Mar-2021	30-Mar-2021	31-Mar-2021
Test Site	RL	RL	RL	SC
Kit Part Code	09289267190	C58957	06R91	06R87
Kit Lot No.	516394	971257	23562FN00	25047FN00
Kit Exp. Date	30-Apr-2021	30-Jun-2021	30-Apr-2021	06-Jun-2021

¹Results are reported as Units per mL (U/mL); positive/reactive results are noted in bold red and negative results are in non-bold black.

²Results 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.

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

SC = SeraCare; RL = Reference Lab

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.