

AccuSet™ SARS-CoV-2 Performance Panel 0820-0410 / (Batch #10497051)

OVERVIEW

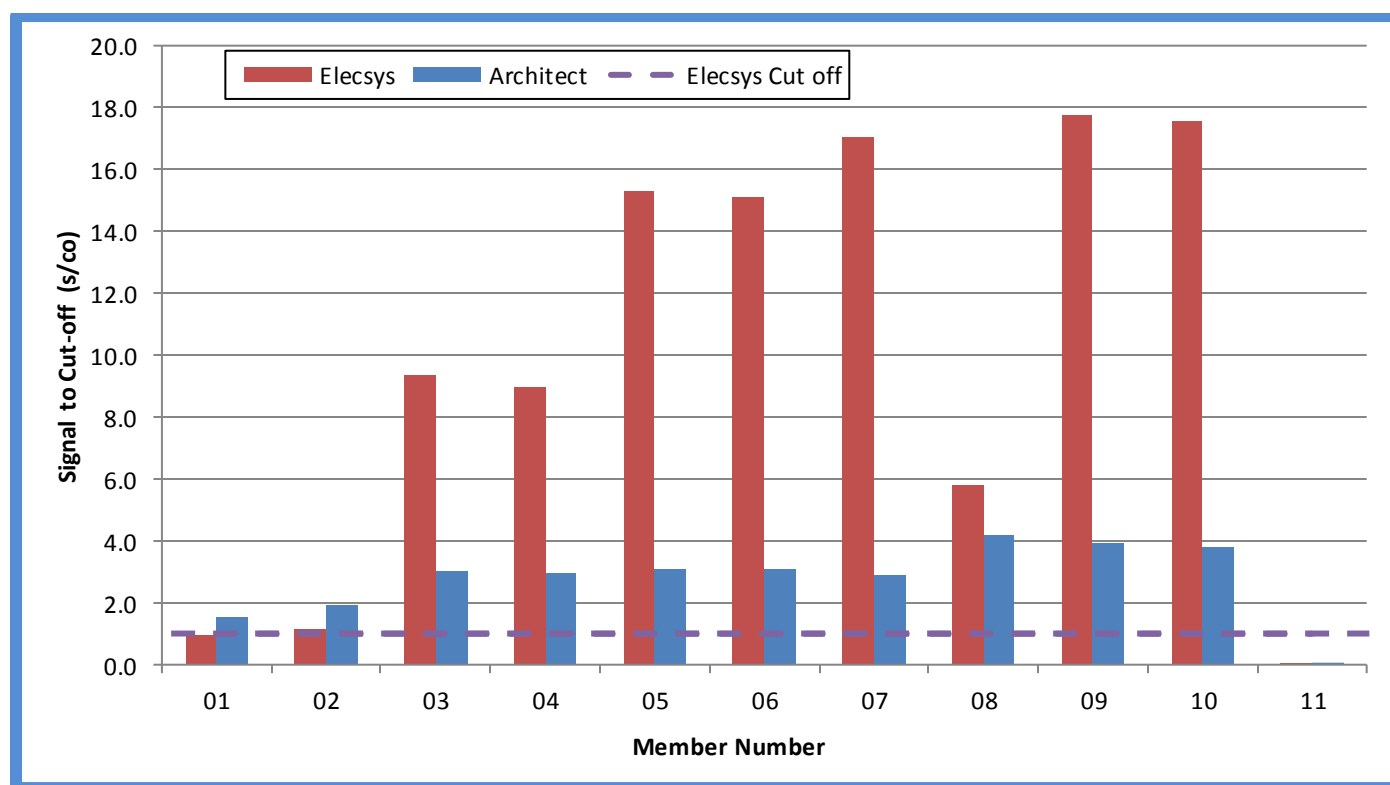
AccuSet™ SARS-CoV-2 Performance Panel (0820-0410 / Batch #10497051) is an 11-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to SARS-CoV-2. Each sample represents 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.

AccuSet™ SARS-CoV-2 Performance Panel



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 #	Bleed 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

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

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SARS-CoV-2 Antibody

Panel Member	ABBOTT ARCHITECT SARS-CoV-2 IgG (s/co) ^{1,2}	ROCHE cobas® Elecsys® Anti-SARS-CoV-2 (COI) ^{2,3}	EUROIMMUN Anti-SARS-CoV-2 IgA (s/co) ^{1,2}	EPITOPE DIAGNOSTICS COVID-19 IgM ELISA (s/co) ^{1,2}
01	1.56	0.96	2.15	0.53
02	1.96	1.14	1.45	0.47
03	3.01	9.38	5.77	0.67
04	2.96	9.00	5.34	0.52
05	3.10	15.33	2.14	0.76
06	3.07	15.10	2.08	0.54
07	2.91	17.03	1.46	0.50
08	4.19	5.79	10.08⁴	0.57
09	3.92	17.79	8.04	0.46
10	3.79	17.59	7.69	0.42
11	0.03	0.07	0.63	0.45
Test Date	03-Jun-20	04-Jun-20	04-Jun-20	04-Jun-20
Test Site	SC	RL	SC	SC
Kit Part Code	06R86	09203095190	EI 2606-9601 A	KT-1033
Kit Lot No.	15016M800	496298	E200427BC	P791U
Kit Exp. Date	07/11/2020	06/30/2020	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.

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: 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.

AccuSet™ SARS-CoV-2 Performance Panel (0820-0410)

INTENDED USE

The AccuSet™ SARS-CoV-2 Performance Panel (0820-0410) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot SARS-CoV-2 test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is an 11-member panel consisting of undiluted, naturally occurring plasma samples collected from individual donors positive for SARS-CoV-2 antibodies. Each sample represents a single collection event. No preservatives were added.

Material Number: 0820-0410, 1 vial per member
10 Positive members, 1.0 mL per vial
1 Negative member, 1.0 mL per vial

STORAGE

Panel members should be stored frozen at -20°C or colder. SeraCare recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation. After opening, record the date opened and the expiration date on the vial. Multiple freeze-thaw cycles are not recommended and may have variable adverse effects on test results. To prevent leakage, store vials upright.

INTERPRETATION OF RESULTS

The Data Sheet for AccuSet™ SARS-CoV-2 Performance Panel (0820-0410) is available at www.seracare.com. The Data Sheet lists results for panel members generated using commercially-available screening, monitoring, and confirmatory test methods. Tests were performed at SeraCare or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Information regarding specific test methods is available on the data sheet. Data Sheets are updated when new data are available.

LIMITATIONS

AccuSet™ SARS-CoV-2 Performance Panel is offered 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.

SAFETY PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Follow Universal Precautions¹. The units that make up this panel were tested and found negative for anti-HIV, HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

These materials should be disposed of in a manner that will inactivate pathogenic agents.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact SeraCare at 508.244.6400.

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