



**ACCESS**  
Immunoassay Systems

## Instructions For Use

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**ACCESS SARS-CoV-2 IgG**  
**SARS-CoV-2 IgG**

**REF** C58961

**For Use Under the Emergency Use Authorization (EUA) Only**

**For *In Vitro* Diagnostic Use**

**Rx Only**

**FOR USE ON ACCESS FAMILY OF IMMUNOASSAY SYSTEMS**

### ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

## PRINCIPLE

### CAUTION

**For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.**

### INTENDED USE

The Access SARS-CoV-2 IgG assay is a paramagnetic particle, chemiluminescent immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, serum separator tubes and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate). The Access SARS-CoV-2 IgG assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of the Access SARS-CoV-2 IgG assay after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the Access SARS-CoV-2 IgG assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Access SARS-CoV-2 IgG assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

## SUMMARY AND EXPLANATION

Coronavirus disease-2019 (COVID-19) is caused by a novel coronavirus known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which has spread worldwide in 2020 causing a global pandemic. COVID-19 is characterized by fatigue, fever, cough, shortness of breath and other respiratory symptoms.<sup>1</sup> The virus uses the transmembrane receptor angiotensin-converting enzyme 2 (ACE-2) to infect epithelial cells in the airways and lungs.<sup>2</sup> Some individuals infected with SARS-CoV-2 have no, or mild symptoms while others develop severe respiratory distress requiring mechanical ventilation.<sup>3</sup> Infected individuals develop an immune response to the virus in the form of anti-SARS-CoV-2 IgM and IgG antibodies over the course of days to weeks.<sup>4</sup> Testing for the presence of IgM/IgG antibodies to SARS-CoV-2 can help to inform clinical management of patients with current, or recent COVID-19.

## METHODOLOGY

The Access SARS-CoV-2 IgG assay is a two-step enzyme immunoassay. A sample is added to a reaction vessel with buffer, and paramagnetic particles coated with recombinant SARS-CoV-2 protein specific for the receptor binding domain (RBD) of the S1 protein.<sup>5</sup> After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. A monoclonal anti-human IgG alkaline phosphatase conjugate is added and the conjugate binds to the IgG antibodies captured on the particles. A second separation and wash step remove unbound conjugate. A chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is compared to the cut-off value defined during calibration of the instrument.

## SPECIMEN

### SPECIMEN STORAGE AND STABILITY

Stability				
Specimen	Type	20°C to 25°C (hours)	2°C to 8°C (hours)	-20°C or colder (days)
Serum	Serum separator tube	8	48	30
Plasma	Heparin EDTA Citrate	8	48	30

Thaw samples only once.

### SPECIMEN COLLECTION AND PREPARATION

#### Blood Specimen

1. The role of preanalytical factors in laboratory testing has been described in a variety of published literature.<sup>6,7</sup> To minimize the effect of preanalytical factors observe the following recommendations for handling and processing blood samples:<sup>6</sup>

- A. Collect all blood samples observing routine precautions for venipuncture.
    - a. Follow blood collection tube manufacturer's recommendations for centrifugation.
    - b. Ensure residual fibrin and cellular matter has been removed prior to analysis.
  - B. Allow serum samples to clot completely before centrifugation in a vertical position, with the collection tube closure directed upwards.
    - a. Follow the tube manufacturer's recommendations for the length of serum/cells contact time before centrifuging samples. The clotting may be slower at cooler temperatures, or if the patient is on anticoagulant therapy.
2. Each laboratory should determine the acceptability of its own blood collection tubes and separation products that are in use. There may be variations in these products between manufacturers and between manufacturing lots.
  3. Alternate collection types may be appropriate if the laboratory has established its own performance characteristics as defined by applicable law.
  4. Avoid assaying lipemic or hemolyzed samples.

## REAGENTS

### CONTENTS

#### Access SARS-CoV-2 IgG Reagent Pack

Ref. No. C58961, 200 determinations, 2 packs, 100 tests/pack

Well	Ingredients
R1a:	Paramagnetic particles coated with recombinant SARS-CoV-2 protein in TRIS buffer with surfactant, protein (bovine), < 0.1% sodium azide and 0.1% ProClin* 300.
R1b:	MES buffer, surfactant, protein (bovine), < 0.1% sodium azide and 0.1% ProClin 300.
R1c:	MES buffer, mouse monoclonal anti-human IgG antibody alkaline phosphatase conjugate, surfactant, protein (bovine) < 0.1% sodium azide and 0.1% ProClin 300.
R1d:	TRIS buffer, surfactant, protein (bovine), < 0.1% sodium azide and 0.1% ProClin 300.
R1e:	TRIS buffer, surfactant, protein (bovine), < 0.1% sodium azide and 0.1% ProClin 300.

\*ProClin™ is a trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow.


### WARNING AND PRECAUTIONS

- **For *in vitro* diagnostic use.**
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This test has been authorized only for the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices,<sup>8</sup> regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for

decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.

- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

## REACTIVE INGREDIENTS

 <b>CAUTION</b>
<b>Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.</b>

## GHS HAZARD CLASSIFICATION

SARS-CoV-2 IgG Particles  
(Compartment R1a)

WARNING



H317

May cause an allergic skin reaction.

H412

Harmful to aquatic life with long lasting effects.

P273

Avoid release to the environment.

P280

Wear protective gloves, protective clothing and eye/face protection.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before use.

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SARS-CoV-2 IgG Conjugate  
Diluent (Compartment R1b)

WARNING



H317

May cause an allergic skin reaction.

H412

Harmful to aquatic life with long lasting effects.

P273

Avoid release to the environment.

P280

Wear protective gloves, protective clothing and eye/face protection.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before use.

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SARS-CoV-2 IgG Conjugate  
(Compartment R1c)

WARNING



H317

May cause an allergic skin reaction.

H412

Harmful to aquatic life with long lasting effects.

P273

Avoid release to the environment.

P280

Wear protective gloves, protective clothing and eye/face protection.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before use.

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SARS-CoV-2 IgG Ancillary  
Diluent (Compartment R1d)

WARNING



H316

Causes mild skin irritation.

H317

May cause an allergic skin reaction.

H319

Causes serious eye irritation.

H412

Harmful to aquatic life with long lasting effects.

P273

Avoid release to the environment.

P280

Wear protective gloves, protective clothing and eye/face protection.

P332+P313

If skin irritation occurs: Get medical advice/attention.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P337+P313

If eye irritation persists: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before use.

Ethoxylated lauryl alcohol 1 - < 3%


reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SARS-CoV-2 IgG Ancillary  
Diluent (Compartment R1e)

WARNING



H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use.
	Ethoxylated lauryl alcohol 1 - < 3%
	reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

	Safety Data Sheet is available at <a href="http://beckmancoulter.com/techdocs">beckmancoulter.com/techdocs</a>
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#### MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access SARS-CoV-2 IgG Calibrator  
Provided as one negative and one positive for SARS-CoV-2 IgG  
Ref. No. C58963
2. QC (Quality Control) materials: Access SARS-CoV-2 IgG QC  
Ref. No. C58964
3. Access Substrate  
Ref. No. 81906
4. Access Wash Buffer II, Ref. No. A16792  
UniCel DxI Wash Buffer II, Ref. No. A16793

#### REAGENT PREPARATION

Provided ready to use.

#### REAGENT STORAGE AND STABILITY

Stability	
Unopened at 2°C to 10°C	Up to stated Expiration Date
After opening at 2°C to 10°C	28 days

- Store upright.
- Refrigerate at 2°C to 10°C for a minimum of two hours before use on the instrument.
- Signs of possible deterioration are a broken elastomeric layer on the pack or quality control values out of range.
- If the reagent pack is damaged (e.g., a broken elastomer), discard the pack.
- Discard reagents if any discoloration is observed.

## **CALIBRATION**

### **CALIBRATION INFORMATION**

An active calibration point is required for all tests. For the SARS-CoV-2 IgG assay, a calibration is required every 28 days. See calibrator Instructions for Use (IFU) for additional calibration information. Refer to the appropriate system manuals and/or Help system for information on calibration method, configuring calibrators, calibrator test request entry, and reviewing calibration data.

## **QUALITY CONTROL**

Quality control materials simulate the characteristics of samples and are essential for monitoring the system performance of immunochemical assays. Include quality control materials in each 24-hour time period, or as required by individual laboratory procedures, because samples may be processed at any time in a “random access” format rather than a “batch” format.

Include Access SARS-CoV-2 IgG QC or other commercially available quality control materials that cover at least two levels of analyte.

More frequent use of quality controls or the use of additional controls is left to the discretion of the operator, based upon good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer’s instructions for reconstituting and storing controls. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results that were generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

## **TESTING PROCEDURE(S)**

### **PROCEDURE**

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
  - A. The system default unit of measure for sample results is S/CO.
2. Mix the contents of a new (unpunctured) reagent pack by gently inverting the pack several times before loading it on the instrument. Do not invert an open (punctured) pack.
3. Use twenty (20) µL of sample for each determination, in addition to the sample container and system dead volumes, when requesting the SARS-CoV-2 IgG assay.
4. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

### **LIMITATIONS**

#### **For Use under an Emergency Use Authorization Only**

1. Do not dilute samples as this could lead to incorrect results.
2. For assays that employ antibodies, the possibility exists for interference by heterophile antibodies in the test sample. Patients who are regularly exposed to animals, or are subjected to medical treatments that utilize immunoglobulins or immunoglobulin fragments, may produce human anti-animal antibodies, e.g. HAMA, that interfere with immunoassays. These interfering antibodies may cause erroneous results.
3. Other potential interferences could be present in the sample and may cause erroneous results in immunoassays. Some examples that are documented in literature include rheumatoid factor, endogenous alkaline phosphatase, fibrin, and proteins capable of binding to alkaline phosphatase.<sup>9</sup> Carefully evaluate results if the sample is suspected of having these types of interferences.
4. The Access SARS-CoV-2 IgG assay results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.
5. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
6. Negative results do not preclude acute SARS-CoV-2 infection. IgG antibodies may not be detected in the first few days of infection; the sensitivity of the Access SARS-CoV-2 IgG assay early after infection is unknown. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
7. A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.
8. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for an alternative serology test to confirm an immune response. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
9. False positive test results for IgG antibodies can occur due to cross-reactivity with pre-existing antibodies or from other possible causes.
10. This test is not to be used for screening donated blood.

### **Conditions of Authorization for the Laboratory**

The Access SARS-CoV-2 IgG assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the Authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-serological> or at <http://www.beckmancoulter.com>. Authorized laboratories using the Access SARS-CoV-2 IgG (“your product” in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories\* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product will use it as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use this product are not permitted.
3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of this product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and Beckman Coulter, Inc.



(Customer Technical Support: 1-800-854-3633; Customer portal: [www.beckmancoulter.com](http://www.beckmancoulter.com)) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics.

6. All laboratory personnel using your product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Beckman Coulter, Inc., authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

\*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests" as "authorized laboratories."

## RESULTS INTERPRETATION

Test results are determined automatically by the system software. Detection of analyte in the sample is determined from the measured light production by means of the stored calibration data. Results are reported as reactive or non-reactive. Results located 20% below the cut-off are interpreted as equivocal, and should be carefully reviewed.

For samples in the equivocal zone, it is recommended that a new sample be collected and tested approximately one to two weeks later using the Access SARS-CoV-2 IgG assay. A conversion from equivocal to reactive for IgG antibody should be considered as evidence of seroconversion due to recent infection. The equivocal result (gray zone)  $> 0.80$  to  $< 1.00$  S/CO must be saved in memory by the user. A flag ("GRY"), which is automatically reported, allows the user to quickly see a result located within the equivocal range. Refer to the appropriate system manuals and/or Help system for complete instructions for set up of gray zone for a qualitative assay and reviewing sample results.

Result	Interpretation	Reporting Instructions
$\leq 0.80$ S/CO SARS-CoV-2 IgG	Non-Reactive	Report result as non-reactive for SARS-CoV-2 IgG antibodies
$> 0.80$ to $< 1.00$ S/CO SARS-CoV-2 IgG	Equivocal	Report as equivocal for SARS-CoV-2 IgG antibodies. Collect a new sample one or two weeks later and test.
$\geq 1.00$ S/CO SARS-CoV-2 IgG	Reactive	Report result as reactive for SARS-CoV-2 IgG antibodies

## PERFORMANCE CHARACTERISTICS

### PERFORMANCE CHARACTERISTICS

#### POSITIVE AGREEMENT

The positive percent agreement (PPA) of the Access SARS-CoV-2 IgG assay was evaluated in 192 serum and plasma samples from symptomatic individuals diagnosed with SARS-CoV-2 by PCR methods from France and the United States. The results are presented in the following table, classified by days between the positive PCR test and the blood sample draw. The 95% confidence interval was determined by the Wilson Score method.

Days between positive PCR and Sample Collection	Total Samples	Number Non-reactive	Number Reactive	Number Equivocal	PPA (95% CI)
≤ 7	33	8	25	0	75.8% (59.0 - 87.2%)
8-14	64	3	61	0	95.3% (87.1 - 98.4%)
≥ 15	95	1	92	2	96.8% (91.1 - 98.9%)

The positive percent agreement of the Access SARS-CoV-2 IgG assay in serum and plasma specimens >18 days after a positive PCR was 100.0% (51/51; 95% CI 93.0 – 100.0%). The positive percent agreement for all tested specimens was 92.7% (178/192; 95% CI 88.1 - 95.6%).

### LONGITUDINAL STUDY

Seroconversion was evaluated in a panel of 75 serum and plasma specimens collected from 20 symptomatic and PCR-positive individuals with 2 or more post PCR blood draws. Of the 20 individual patients, 13 patients showed positive results in all blood draws, 2 patients showed negative results for all draws, and 5 individual patients showed SARS-CoV-2 IgG seroconversion. The following table shows the 5 individual patient seroconversion results.

Patient	Draw	Days post-PCR	Result (S/CO)	Interpretation
A	1	0	0.27	Non-reactive
	2	6	14.30	Reactive
B	1	5	0.15	Non-reactive
	2	7	1.57	Reactive
	3	8	4.58	Reactive
	4	10	20.18	Reactive
C	1	0	0.05	Non-reactive
	2	11	60.86	Reactive
D	1	0	0.15	Non-reactive
	2	4	17.04	Reactive
	3	6	40.76	Reactive
	4	8	50.54	Reactive
	5	10	55.93	Reactive
	6	13	52.59	Reactive
E	1	14	0.32	Non-reactive
	2	17	53.38	Reactive
	3	20	60.84	Reactive

### NEGATIVE PERCENT AGREEMENT

The negative percent agreement (NPA) of the Access **SARS-CoV-2** IgG assay was evaluated in a study of 1,400 samples collected prior to December 2019\* in France and the United States. This total includes 1,000 samples from blood

donors in France and 200 samples each from routine clinical laboratory diagnostic samples in France and the United States. Based on this evaluation, the overall negative percent agreement of the Access SARS-CoV-2 IgG assay is 99.6% (1395/1400), with a 95% confidence interval of 99.2% - 99.8% determined by the Wilson Score method.

Population	Total Samples	Number Non-Reactive	Number Reactive	Number Equivocal	NPA (95% CI)
Blood Donors (France)	1,000	997	2	1	99.7% (99.1 - 99.9%)
Diagnostic Samples (France)	200	199	1	0	99.5% (97.2 - 99.9%)
Diagnostic Samples (United States)	200	199	0	1	99.5% (97.2 - 99.9%)
Total	1,400	1,395	3	2	99.6% (99.2 - 99.8%)

\*It has been shown that over 90% of the adult population have antibodies to all four common circulating coronaviruses.<sup>10,11</sup>

### INTERFERING SUBSTANCES

High concentrations of endogenous serum components were assessed for interference in the Access SARS-CoV-2 IgG assay. The test protocol was based on CLSI EP07, Interference Testing in Clinical Chemistry, 3rd Edition.<sup>12</sup> Human serum was spiked with a patient sample containing SARS-CoV-2 IgG antibodies to achieve a positive reactivity in the Access SARS-CoV-2 IgG assay. None of the substances tested demonstrated significant interference in the Access SARS-CoV-2 IgG assay as defined by a shift in concentration greater than 20% using the test concentrations indicated in the table below.

Substance	Interferent Concentration Tested
Bilirubin (conjugated)	43 mg/dL
Bilirubin (unconjugated)	43 mg/dL
Hemoglobin	300 mg/dL
Triglycerides (Triolein)	1,500 mg/dL

### CROSS REACTIVITY

Cross-reactivity of the Access SARS-CoV-2 IgG assay was evaluated by testing serum and plasma samples for each of the potentially cross-reacting conditions listed in the following table. No crossreactivity was observed for the Access SARS-CoV-2 IgG assay.

Category	Number of Samples	Number of Reactive Samples	Number of Non-Reactive Samples
Anti-Influenza A	5	0	5
Anti-Influenza B	5	0	5
Anit-Hepatitis C Virus (HCV)	5	0	5

<b>Category</b>	<b>Number of Samples</b>	<b>Number of Reactive Samples</b>	<b>Number of Non-Reactive Samples</b>
Anti-Hepatitis B Virus (HBV)	5	0	5
Anti-HIV	10	0	10
Anti-Nuclear Antibodies (ANA)	5	0	5
Anti-Adenovirus Positive IgG	2	0	2
Cytomegalovirus (CMV) IgG	7	0	7
Rheumatoid Factor (RF)	5	0	5

## **ADDITIONAL INFORMATION**

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May be covered by one or more pat. -see [www.beckmancoulter.com/patents](http://www.beckmancoulter.com/patents).

### **REVISION HISTORY**

#### **Revision A**

New release.


### **SYMBOLS KEY**

Glossary of Symbols is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs) (document number C02724).

## REFERENCES

1. Bhatraju PK, Ghassemieh BJ, Nichols M, et al. COVID-19 in critically ill patients in the Seattle region – Case Series. *N Engl J Med.* 2020 Mar 30. doi: 10.1056/NEJMoa2004500. [Epub ahead of print]
2. Walls AC, Park YJ, Tortorici MA et al. Structure, Function and Antigenicity of the SARS-CoV-2 Spike Glycoprotein. *Cell.* 2020 Apr 16;181(2):281-292.e6. doi: 10.1016/j.cell.2020.02.058. Epub 2020 Mar 9.
3. Chavez S, Long B, Koyfman A and Liang SY. Coronavirus Disease (COVID-19): A primer for emergency physicians. *Am J Emerg Med.* 2020 Mar 24. pii: S0735-6757(20)30178-9. doi: 10.1016/j.ajem.2020.03.036. [Epub ahead of print]
4. Zhao J, Yuan Q, Wang H et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019 (2020). *Clinical Infectious Diseases.* Published electronically on March 28, 2020.
5. Ni L, Ye F, Cheng M-L, et al. Detection of SARS-CoV-2-specific humoral and cellular immunity in COVID-19 convalescent individuals. *Immunity,* 2020. doi: <https://doi.org/10.1016/j.immuni.2020.04.023>
6. Approved Guideline - Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests, GP44-A4. May 2010. Clinical and Laboratory Standards Institute.
7. Approved Guideline - Collection of Diagnostic Venous Blood Specimens, GP41, 7<sup>th</sup> Edition, April 2017. Clinical and Laboratory Standards Institute.
8. Approved Guideline - Protection of Laboratory Workers From Occupationally Acquired Infections, M29-A4, 4<sup>th</sup> Edition, May 2014. Clinical and Laboratory Standards Institute.
9. Lingwood D, Ballantyne JS., Alkaline phosphatase-immunoglobulin conjugate binds to lipids in vitro, independent of antibody selectivity. *Journal of Immunological Methods* 2006; 311: 174-177.
10. Severance EG, Bossis I, Dickerson FB et al. Development of a Nucleocapsid-Based Human Coronavirus Immunoassay and Estimates of Individuals Exposed to Coronavirus in a U.S. Metropolitan Population. *Clin. Vaccine Immunol.* 2008; 15:12, 1805-1810.
11. Theel ES, Slev P, Wheeler S. et al. The Role of Antibody Testing for SARS-CoV-2: Is There One? *J Clin Microbiol.* 2020 Apr 29. pii: JCM.00797-20. doi: 10.1128/JCM.00797-20. [Epub ahead of print]
12. Approved Guideline - Interference Testing in Clinical Chemistry, EP07 3<sup>rd</sup> Edition. April 2018. Clinical and Laboratory Standards Institute.

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