

# ACCESS

## Immunoassay Systems Instructions For Use

# Access SARS-CoV-2 IgG II

SARS-CoV-2 IgG  
REF C69057

For Use Under an 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.

The concentration of SARS-CoV-2 IgG in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. Values obtained with different assay methods should not be used interchangeably.

The results of this semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from reinfection.

### INTENDED USE

The Access SARS-CoV-2 IgG II assay is a paramagnetic particle, chemiluminescent immunoassay intended for the semi-quantitative and qualitative detection of IgG antibodies to SARS-CoV-2 in human plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate). The Access SARS-CoV-2 IgG II 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. The Access SARS-CoV-2 IgG II should not be used to diagnose or exclude acute SARS-CoV-2 infection. 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 results to the appropriate public health authorities.

The sensitivity of the Access SARS-CoV-2 IgG II assay early 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 II assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Access SARS-CoV-2 IgG II 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.

Evidence shows that recovered COVID-19 patients can generate immunoglobulin G (IgG)-type antibodies specifically binding to various structure proteins of SARS-CoV-2 after the onset of disease, at variable levels.<sup>5,6,7</sup> A significant correlation between severity of illness and neutralizing antibody titers specific to the receptor binding domain (RBD) of the S1 protein has been identified.<sup>8,9,10</sup>

Multiple laboratories and companies are working to rapidly develop vaccine candidates in a short period of time employing vaccine strategies targeting the RBD of the S1 protein<sup>10,11,12</sup> with initial data indicating that an antibody response from this region may be neutralizing to SARS-CoV-2. The ability to identify neutralizing antibodies to the RBD of the S1 protein may prove to be an important tool to study the immune response of SARS-CoV-2.

## **METHODOLOGY**

The Access SARS-CoV-2 IgG II 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>8</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 directly proportional to the concentration of SARS-CoV-2 IgG antibody in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

The Access SARS-CoV-2 IgG II test (COVG/dCOVG) is to be used with the fully automated Access Family of Immunoassay Analyzers including the standalone Access 2, UniCel DxI 600, and UniCel 800 analyzers and integrated chemistry/immunoassay platforms; UniCel DxI 600i, UniCel DxI 680i, UniCel DxI 880i, UniCel DxI 660i and UniCel DxI 860i.

## SPECIMEN

### SPECIMEN STORAGE AND STABILITY

Stability				
Specimen	Type	20°C to 25°C (hours)	2°C to 8°C (days)	-20°C or colder (days)
Plasma	Lithium Heparin K2 and K3 EDTA Sodium Citrate	48	7	30

Do not thaw samples more than two times.

### 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>13,14</sup> To minimize the effect of preanalytical factors observe the following recommendations for handling and processing blood samples:<sup>13</sup>
  - i. Collect all blood samples observing routine precautions for venipuncture.
  - ii. Follow blood collection tube manufacturer's recommendations for centrifugation.
  - iii. Ensure residual fibrin and cellular matter has been removed prior to analysis.
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 II Reagent Pack

Ref. No. C69057, 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.

Well	Ingredients
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 Emergency Use Authorization (EUA) only.
- For *in vitro* diagnostic use.
- The results of this semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from infection.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is 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>15</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

### ⚠ CAUTION

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.

## GHS HAZARD CLASSIFICATION

SARS-CoV-2 IgG II Particles      WARNING  
(Compartment R1a)



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

WARNING



H317

H412

P273

P280

P333+P313

P362+P364

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

Avoid release to the environment.

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

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

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 II  
Conjugate (Compartment R1c)

WARNING



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

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%
	<b>REVOKE</b>
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.

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

WARNING

Ethoxylated laurylalcohol 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%



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 laurylalcohol 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%

SDS

Safety Data Sheet is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs)

## MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access SARS-CoV-2 IgG II Calibrator  
Provided as zero and approximately 5.0, 25.0, 100, 200 and 450 AU/mL  
Ref. No. C69058

2. QC (Quality Control) materials: Access SARS-CoV-2 IgG II QC  
Ref. No. C69059

3. Access Sample Diluent A  
Ref. No. 81908  
Diluent Pack Ref. No. A79783 (for use with the UniCel DxI system onboard dilution feature.)

4. Access Substrate  
Ref. No. 81906

5. 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.
- Do not use reagents past the expiration date.

## CALIBRATION

### CALIBRATION INFORMATION

An active calibration is required for all tests. For the SARS-CoV-2 IgG II 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

Please refer to Quality Control Instructions for Use.

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 II QC that covers 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 AU/mL.
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)  $\mu$ L of sample for each determination in addition to the sample container and system dead volumes when requesting the Access SARS-CoV-2 IgG II assay. Use twenty-five (25)  $\mu$ L of sample in addition to the sample container and system dead volumes for each determination run with the Dxl system onboard dilution feature (test name: dCOVG). Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.
  - a. Select COVG as the test name for assaying samples containing SARS-CoV-2 IgG concentrations up to the concentration of the Access SARS-CoV-2 IgG II S5 calibrator.
  - b. UniCel Dxl users use the UniCel Dxl onboard dilution feature (test name: dCOVG) for assaying samples containing SARS-CoV-2 IgG concentration greater than the Access SARS-CoV-2 IgG II S5 calibrator.

### LIMITATIONS

1. Use of Access SARS-CoV-2 IgG II is limited to laboratory personnel who have been trained. Not for home use.
2. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.
3. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
4. This assay has not been evaluated with fingerstick specimens. This test is not authorized for use with fingerstick whole blood.
5. The clinical applicability of a quantitative or semi-quantitative result is currently unknown and cannot be

interpreted as an indication or degree of immunity nor protection from reinfection, nor compared to other SARS-CoV-2 antibody assays.

6. Results obtained with the assay may not be used interchangeably with values obtained with different manufacturers' test methods.
7. 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.
8. 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>16</sup> Carefully evaluate results if the sample is suspected of having these types of interferences.
9. The Access SARS-CoV-2 IgG II 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.
10. Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. 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 II assay early after infection is unknown. Samples should be collected from individuals that are  $\geq$  8 days post symptom onset. Samples should not be tested if collected from individuals less than 8 days post symptom onset. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
12. 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 the antibodies that are detected are not present during the stage of disease in which a sample is collected.
13. 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.
14. False positive test results for IgG antibodies can occur due to cross-reactivity with pre-existing antibodies or from other possible causes.
15. This test is not to be used for screening donated blood.
16. The performance of this device has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the results from this assay should not be interpreted as an indication or degree of protection from infection after vaccination.
17. The performance of this test was established based on the evaluation of a limited number of clinical specimens. The samples for the negative agreement study were all collected prior to December 2019. The samples from the positive percent agreement were collected from New Jersey, USA and two sites in France (Amiens and Lyons) from February 2020 to May 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

## Conditions of Authorization for the Laboratory

The Access SARS-CoV-2 IgG II assay Letter of Authorization, along with the Authorized Fact Sheet for Healthcare

Access SARS-CoV-2 IgG

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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/in-vitro-diagnostics-euas> or at <http://www.beckmancoulter.com>. Authorized laboratories using the Access SARS-CoV-2 IgG II ("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 must 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 must use your product as outlined in the authorized labeling. 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 your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories must collect information on the performance of this product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: 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 must 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. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. The test results can be viewed using the appropriate screen. If the controls are not valid or control results are outside of expected ranges the patient results cannot be interpreted. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

Result	Interpretation	Reporting Instructions
< 10 AU/mL SARS-CoV-2 IgG II	Non-Reactive	Report result as non-reactive for SARS-CoV-2 IgG antibodies
≥ 10 AU/mL SARS-CoV-2 IgG II	Reactive	Report result as reactive for SARS-CoV-2 IgG antibodies, with numeric AU/mL value within the

Result	Interpretation	Reporting Instructions
		measuring interval

## MEASURING INTERVAL

The analytical measuring range extends from 2.00 AU/mL to 450 AU/mL.

- Numerical results below 10 AU/mL should not be reported outside of the laboratory. Report the result as "Non-Reactive".
- The highest Access SARS-CoV-2 IgG II calibrator (S5) is targeted at the upper limit of the analytical measuring range (450 AU/mL). If numerical results exceed the upper limit of the measuring interval, report the result as "Reactive > [S5 value]". Alternatively, dilute one volume of sample with nineteen volumes of Access Sample Diluent A.
- When the DxI system onboard dilution feature is used, the system will report an extended range from 380 AU/mL or up to 9,000 AU/mL.

Refer to the appropriate system manuals and/or Help system for instruction on entering a sample dilution in a test request. The system reports the results adjusted for the dilutions.

Onboard Dilution Feature for use on the UniCel DxI systems:

The DxI system onboard dilution feature automates the dilution process, using one volume of sample with nineteen volumes of Access Sample Diluent A, allowing results to be reported up to 9,000 AU/mL. The system reports the results adjusted for the dilution.

## PERFORMANCE CHARACTERISTICS

### PERFORMANCE CHARACTERISTICS

#### POSITIVE AGREEMENT

The positive percent agreement (PPA) of the Access SARS-CoV-2 IgG II assay was evaluated in 126 individual 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 symptom onset and the blood sample draw. The 95% confidence interval was determined by the Wilson Score method.

Days post symptom onset	Total Samples	Number Non-reactive	Number Reactive	PPA (95% CI)
0-7	11	2	9	81.8% (52.3-94.9%)
8-14	24	1	23	95.8% (79.8-99.3%)
≥ 15	91	1	90	98.9% (94.0-99.8%)

#### NEGATIVE AGREEMENT

The negative percent agreement (NPA) of the Access SARS-CoV-2 IgG II assay was evaluated in a study of 93 samples collected prior to December 2019\*. Based on this evaluation, the overall negative percent agreement of

the Access SARS-CoV-2 IgG II assay is 100.0% (93/93), with a 95% confidence interval of 96.0-100.0% determined by the Wilson Score method.

Population	Total Samples	Number Non-reactive	Number Reactive	NPA (95% CI)
Diagnostic Samples	93	93	0	100.0% (96.0%-100.0%)

\*It has been shown that over 90% of the adult population have antibodies to all four common circulating coronaviruses.<sup>17,18</sup>

## LINEARITY

The Access SARS-CoV-2 IgG II assay demonstrated acceptable linearity throughout the analytical measuring range of 2.00 AU/mL to 450 AU/mL. Based on CLSI EP06-A,<sup>19</sup> two high SARS-CoV-2 IgG samples, one moderate SARS-CoV-2 IgG sample and two SARS-CoV-2 IgG low samples were each diluted with a negative sample to make 9 discrete dilutions. Four replicates of each dilution and 8 replicates of the negative sample were tested on the Access 2 Immunoassay System.

## PRECISION

A study was performed based on guidance from CLSI EP05-A.<sup>20</sup> A panel consisting of four QC samples (two levels from two QC lots) and six patient samples were tested with three reagent pack lots and two calibrator lots. Samples were run in replicates of three for three days with two runs per day using three Access 2 instruments. A concentration result (AU/mL) was calculated from 12 calibration cycles for each sample replicate.

The Access SARS-CoV-2 IgG II assay exhibits total imprecision  $\leq 15.0\% \text{ CV}$  at concentrations  $\geq 10.0 \text{ AU/mL}$  and standard deviation within  $\pm 1.50 \text{ AU/mL}$  at concentrations  $< 10.0 \text{ AU/mL}$  shown in the tables below.

Sample	n	Mean	Within Run (Repeatability)		Between Run		Between Day	
			AU/mL	SD	%CV	SD	%CV	SD
QC1	1932	0.1	0.02		NA	0.02	NA	0.00
QC1	1944	0.1	0.02		NA	0.02	NA	0.01
Sample 1	1944	0.5	0.02		NA	0.02	NA	0.01
Sample 2	1944	9.4	0.29		NA	0.28	NA	0.24
QC2	1932	26.9	0.95	3.5%	1.00	3.7%	0.00	0.0%
QC2	1932	28.9	1.00	3.5%	0.78	2.7%	0.00	0.0%
Sample 3	1932	32.2	1.17	3.6%	0.89	2.8%	0.67	2.1%
Sample 4	1944	52.3	2.03	3.9%	2.26	4.3%	2.27	4.3%

Sample	n	Mean	Within Run (Repeatability)		Between Run		Between Day	
			SD	%CV	SD	%CV	SD	%CV
Sample 5	1944	106.1	3.83	3.6%	2.76	2.6%	0.01	0.0%
Sample 6	1932	242.8	11.63	4.8%	11.68	4.8%	0.00	0.0%

Sample	n	Mean	Within Laboratory		Reproducibility	
			SD	%CV	SD	%CV
QC1	1932	0.1	0.03	NA	0.04	NA
QC1	1944	0.1	0.03	NA	0.04	NA
Sample 1	1944	0.5	0.03	NA	0.05	NA
Sample 2	1944	9.4	0.47	NA	0.56	NA
QC2	1932	26.9	1.37	5.1%	1.64	6.1%
QC2	1932	28.9	1.26	4.4%	1.53	5.3%
Sample 3	1932	32.2	1.61	5.0%	1.95	6.0%
Sample 4	1944	52.3	3.79	7.2%	4.36	8.3%
Sample 5	1944	106.1	4.72	4.4%	5.70	5.4%
Sample 6	1932	242.8	16.48	6.8%	18.14	7.5%

## INTERFERING SUBSTANCES

High concentrations of endogenous components were assessed for interference in the Access SARS-CoV-2 IgG II assay. The test protocol was based on CLSI EP07, Interference Testing in Clinical Chemistry, 3rd Edition.<sup>21</sup> Endogenous substances were spiked in two (2) positive samples containing SARS CoV-2 IgG antibodies (one low and one moderate) and in one (1) negative sample. None of the substances tested demonstrated significant interference in the Access SARS-CoV-2 IgG II 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 (intralipid)	1,771 mg/dL

## CROSS REACTIVITY

Cross-reactivity of the Access SARS-CoV-2 IgG II assay was evaluated by testing samples for each of the potentially cross-reacting conditions listed in the following table. No cross-reactivity was observed for the Access SARS-CoV-2 IgG II 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
Anti-Hepatitis C Virus (HCV)	5	0	5
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

## ANALYTICAL SENSITIVITY

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were conducted on the Access 2 Immunoassay System following CLSI guideline EP17-A2<sup>22</sup>. The LoB study included of a minimum of 4 blank samples tested on two reagent lots on one instrument over a minimum of 3 days. The LoD and LoQ studies included a minimum of 6 low level samples tested on two reagent lots and one instrument over a minimum of 5 days.

Parameter	Criteria (AU/mL)
Limit of Blank (LoB)	1.00
Limit of Detection (LoD)	2.00
Limit of Quantitation (LoQ)	2.00 <sup>a</sup>

<sup>a</sup>The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20% CV was met.

## DILUTION RECOVERY

Five human samples containing elevated levels of SARS-CoV-2 IgG with values above the analytical measuring interval were diluted 1:20 with Sample Diluent A using the UniCel Dxl onboard dilution and manual dilutions are

shown in the following table.

Sample	DxI Onboard Dilution AU/mL	Manual Dilution 1:20 AU/mL	% Recovery vs Manual
1	992	952	104%
2	789	815	97%
3	646	605	107%
4	1087	998	109%
5	816	782	104%
Overall Mean % Recovery			104%

## TRACEABILITY

The Access SARS-CoV-2 IgG II is traceable to an internal standard based on agreement of known positive and negative SARS-CoV-2 specimens.

## ADDITIONAL INFORMATION

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other Countries.

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

## REVISION HISTORY

### Revision A

New release.

### Revision B

Typographical error.

### Revision C

Measuring interval edit.

### Revision D

Limitations and Warning and Precaution update.

### Revision E

Change test name.

### Revision F

Edits to formatting. Methodology, Warning and Precautions and Quality Control updates.

## SYMBOLS KEY

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

**REVOKED**

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**EC REP**

Beckman Coulter Eurocenter S.A., 22, rue Juste-Olivier. Case Postale 1044, CH - 1260  
Nyon 1, Switzerland Tel: +41 (0)22 365 36 11



Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.  
[www.beckmancoulter.com](http://www.beckmancoulter.com)

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# ACCESS

Immunoassay Systems  
**Instructions For Use**

# ACCESS SARS-CoV-2 IgG II CALIBRATOR

**SARS-CoV-2 IgG**  
**REF C69058**

For Use Under an 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 II Calibrators are intended to calibrate the Access SARS-CoV-2 IgG II assay for the in vitro semi-quantitative and qualitative detection of SARS-CoV-2 IgG antibodies in human plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate) for use on the Access Immunoassay Systems only.

## SUMMARY AND EXPLANATION

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert Relative Light Unit (RLU) measurements of samples to specific quantitative analyte concentrations.

## TRACEABILITY

The analyte in the Access SARS-CoV-2 IgG II Calibrators are traceable to the manufacturers working calibrators. The traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator, and are specific to the assay methodologies of the Access reagents. The values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Currently no reference standard is available for this assay.

## REAGENTS

### CONTENTS

#### Access SARS-CoV-2 IgG II Calibrator

Ref. No. C69058: S0-S5, 2.0 mL/vial

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C. Do not use calibrators past the expiration date.
- Vial is stable at 2 to 10°C for 90 days after initial use.
- Signs of possible deterioration are quality control values out of range.
- Refer to calibration card for exact concentrations.

<b>S0:</b>	TRIS buffer, surfactant and protein (bovine), < 0.1% sodium azide and 0.5% ProClin* 300.
<b>S1-S5:</b>	TRIS buffer containing human anti-SARS-CoV-2 monoclonal IgG, surfactant and protein (bovine), < 0.1% sodium azide and 0.5% ProClin 300.
<b>Calibration Card:</b>	1

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

## WARNING AND PRECAUTIONS

- For Emergency Use Authorization (EUA) only.
- For *in vitro* diagnostic use.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This product is for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is 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>1</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

### ⚠ CAUTION

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.

## GHS HAZARD CLASSIFICATION

SARS-CoV-2 IgG II S0

WARNING



H317

H412

P273

P280

P333+P313

P362+P364

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

Avoid release to the environment.

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

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

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 II S1 - S5

WARNING



H317

H412

P273

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

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%

<b>SDS</b>	Safety Data Sheet is available at <a href="http://beckmancoulter.com/techdocs">beckmancoulter.com/techdocs</a>
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## **CALIBRATION**

### **CALIBRATION INFORMATION**

The Access SARS-CoV-2 IgG II Calibrators are provided at six levels – zero and approximately 5.0, 25.0, 100, 200, and 450 AU/mL. Assay calibration data are valid up to 28 days.

Run the calibrators in duplicate.

### **TESTING PROCEDURE(S)**

#### **PROCEDURE**

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

#### **PROCEDURAL NOTES**

#### **LIMITATIONS**

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

### **ADDITIONAL INFORMATION**

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other Countries.

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

## REVISION HISTORY

### Revision A

New release.

### Revision B

Warning and Precaution update.

### Revision C

Warning and Precaution update.

## SYMBOLS KEY

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

**REVOKED**

## REFERENCES

- 1 Approved Guideline - Protection of Laboratory Workers From Occupationally Acquired Infections, M29-A4, 4th Edition, May 2014. Clinical and Laboratory Standards Institute.

**REVOKED**

**EC REP**

Beckman Coulter Eurocenter S.A., 22, rue Juste-Olivier. Case Postale 1044, CH - 1260  
Nyon 1, Switzerland Tel: +41 (0)22 365 36 11



Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.  
[www.beckmancoulter.com](http://www.beckmancoulter.com)

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# ACCESS

## Immunoassay Systems Instructions For Use

# ACCESS SARS-CoV-2 IgG II QC

SARS-CoV-2 IgG  
REF C69059

For Use Under an 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 II QC is intended for monitoring system performance of the Access SARS-CoV-2 IgG II assay using the Access Immunoassay Systems only.

### SUMMARY AND EXPLANATION

Quality control (QC) materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access SARS-CoV-2 IgG II immunoassay. In addition, they are an integral part of good laboratory practices. When performing assays with Access reagents for SARS-CoV-2 IgG, include quality control materials to validate the integrity of the assays. The assayed values should fall within the acceptable range if the test system is working properly.

### TRACEABILITY

The analyte in the Access SARS-CoV-2 IgG II QC is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511. The assigned values were established using representative samples from this lot of QC, and are specific to the assay methodologies of the Access reagents. The values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

# REAGENTS

## CONTENTS

### Access SARS-CoV-2 IgG II QC

Ref. No. C69059: QC1-QC2, 4 mL/vial, 3 vials each level

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C. Do not use controls past the expiration date.
- Vial is stable at 2 to 10°C for 30 days after initial use.
- Signs of possible deterioration are quality control values out of range.
- Refer to the QC value card for mean values and standard deviations (SD).

QC1:	Negative: TRIS buffer, defibrinated human plasma negative for anti-SARS-CoV-2, surfactant, protein (bovine), < 0.1% sodium azide and 0.5% ProClin* 300.
QC2:	Positive: TRIS buffer, defibrinated human plasma, human anti-SARS-CoV-2 monoclonal IgG, surfactant, protein (bovine), < 0.1% sodium azide and 0.5% ProClin 300.
QC Value Card:	1

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

## WARNING AND PRECAUTIONS

- For use under an Emergency Use Authorization (EUA) only.
- For *in vitro* diagnostic use.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This product is for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is 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>1</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

### ⚠ CAUTION

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.

## GHS HAZARD CLASSIFICATION

SARS-CoV-2 IgG II QC1

WARNING



H317

H412

P273

P280

P333+P313

P362+P364

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

Avoid release to the environment.

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

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

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 II QC2

WARNING



H317

H412

P273

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

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%

**SDS**

Safety Data Sheet is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs)

## TESTING PROCEDURE(S)

### PROCEDURE

Use the Access Immunoassay System to determine the concentration of SARS-CoV-2 IgG in the Access SARS-CoV-2 IgG II QC materials in the same manner as a sample. 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. More frequent use of controls or the use of additional controls is left to the discretion of the operator, based upon good laboratory practices or the laboratory accreditation requirements and applicable laws. Refer to the appropriate system manuals and/or Help system for information on quality control theory, configuring controls, quality control sample test request entry, and reviewing quality control data.

### REPORTING RESULTS

### EXPECTED RESULTS

For the value assignment of Access SARS-CoV-2 IgG II QC material, select and assay a number of samples that are representative of the entire lot to provide a reliable estimate of the mean value. The mean values and standard deviations are listed on the QC value card. There are variations, such as technique, equipment, or reagents, which may cause results that are different from the listed values. Therefore, each laboratory should establish its own mean values and standard deviations (SD). Patient results should not be reported if QC values are outside of expected ranges.

### PROCEDURAL NOTES

### LIMITATIONS

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

## **ADDITIONAL INFORMATION**

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other Countries.

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

## **REVISION HISTORY**

### **Revision A**

New release.

### **Revision B**

Typographical error.

### **Revision C**

Warning and Precaution update.

### **Revision D**

Warning and Precaution update.

## **SYMBOLS KEY**

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

**REVOKED**

## REFERENCES

- 1 Approved Guideline - Protection of Laboratory Workers From Occupationally Acquired Infections, M29-A4, 4th Edition, May 2014. Clinical and Laboratory Standards Institute.

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Beckman Coulter Eurocenter S.A., 22, rue Juste-Olivier. Case Postale 1044, CH - 1260  
Nyon 1, Switzerland Tel: +41 (0)22 365 36 11



Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.  
[www.beckmancoulter.com](http://www.beckmancoulter.com)

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### Access SARS-CoV-2 IgG II Calibrators

#### INFORMATION FOR USA ONLY

For Use Under the Emergency Use Authorization (EUA) Only

For *In Vitro* Diagnostic Use

Rx Only

REF C69058

The Access SARS-CoV-2 IgG II Instructions for Use (IFU) can be downloaded free of charge at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs)

- This is not the full instructions for use
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product is for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.

Please contact Beckman Coulter Technical Support by phone at 1-800-354-3633, in the United States, if you require a printed copy free of charge or need assistance.

C75480 AB

