



**For use under Emergency Use Authorization only**  
**For *in vitro* diagnostic use only**  
**For prescription use only**

*CareStart*<sup>™</sup>

# **EZ COVID-19 IgM/IgG**

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*Rapid Diagnostic Test for the Detection of IgM/IgG antibodies to SARS-CoV-2*

**Package Insert**  
**(Instructions for Use)**

Revision number: A  
Effective date: Jun. 15, 2021

# CareStart™ EZ COVID-19 IgM/IgG

Rapid diagnostic test for detection of IgM/IgG antibodies to SARS-CoV-2

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**CareStart™ EZ COVID-19 IgM/IgG**Rapid diagnostic test for detection of  
IgM/IgG antibodies to SARS-CoV-2

**For use under the Emergency Use Authorization (EUA) only**  
**For *in vitro* diagnostic use only**  
**For prescription use only**

**Intended Use**

The *CareStart*™ EZ COVID-19 IgM/IgG is an immunochromatographic lateral flow assay intended for the qualitative detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA) and fingerstick whole blood. The *CareStart*™ EZ COVID-19 IgM/IgG 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 *CareStart*™ EZ COVID-19 IgM/IgG should not be used to diagnose or exclude acute SARS-CoV-2 infection.

Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform high or moderate complexity tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of SARS-CoV-2 antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in the 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 *CareStart*™ EZ COVID-19 IgM/IgG 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 *CareStart*™ EZ COVID-19 IgM/IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false-positive results,

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confirmation of positive results should be considered using a second, different SARS-CoV-2 IgG or IgM assay.

The *CareStart™* EZ COVID-19 IgM/IgG is only for use under the Food and Drug Administration's Emergency Use Authorization.

**Summary and Explanation of the Test**

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. This antibody test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, the virus that causes COVID-19, indicating recent or prior infection, by detecting antibodies to SARS-CoV-2 in human blood specimens. Although not everyone infected will develop an antibody response, appropriately validated serology tests, when used broadly, can be useful in understanding how many people have developed an adaptive immune response to the virus and how far the pandemic has progressed. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

**Principles of the Test**

The *CareStart™* EZ COVID-19 IgM/IgG test is an immunochromatographic assay for the detection and differentiation of IgM and/or IgG antibodies to SARS-CoV-2 in human blood specimens. Control antibody, anti-human IgG, and streptavidin (test line for IgM) are immobilized onto a nitrocellulose membrane to form three distinct lines, the control line, the IgG test line, and the IgM test line. The nitrocellulose membrane is attached onto a plastic backing card and combined with the other reagents and pads to construct a test strip. The test strip is encased inside an integrated plastic device with a blood lancet and blood tube. Blood samples are added to the sample well of the test device via the blood tube and the test is initiated by adding assay buffer to the sample well. The sample specimens migrate sequentially through filter pad, conjugate pad, nitrocellulose membrane, and absorbent pad. Antibodies to SARS-CoV-2 in sample specimens interact with the recombinant SARS-CoV-2 antigen (SARS-CoV-2 nucleocapsid and spike protein S1 RBD) that is conjugated to colloidal gold nanobeads and biotin to form an immune complex while it migrates through the conjugate pad. SARS-CoV-2 IgM antibodies react with the gold-conjugated SARS-CoV-2 antigen and biotin-conjugated anti-human IgM. SARS-CoV-2 IgG antibodies only react with the gold-conjugated SARS-CoV-2 antigen. The immune complexes migrate through the nitrocellulose membrane and bind to each respective test line. The IgM immune complexes bind to the streptavidin region (IgM test line, "M") on the membrane to generate a purple-colored line to indicate a positive IgM result. The IgG immune complexes bind to the anti-human IgG region (IgG test line, "G") on the membrane to generate a purple-colored line to indicate a positive IgG result. The gold-conjugated chicken IgY migrates through the membrane and binds to the control antibody (anti-chicken IgY) in the control region to generate a red-colored line (control line,

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“C”). The test results should be interpreted 10 minutes after the addition of buffer to the sample well. The test results should not be interpreted after 20 minutes. The color intensity in the test region will vary. Any faint colored line(s) in the test region(s) should be considered as positive.

The presence of two lines marked by “C” and “G” indicates a SARS-CoV-2 IgG positive result. The presence of two lines marked by “C” and “M”, indicates a SARS-CoV-2 IgM positive result. The presence of three lines “C”, “G,” and “M”, indicates positive results for both SARS-CoV-2 IgG and IgM. The appearance of only the control line “C” indicates negative. If the control line does not appear, regardless of the presence of “G” or “M” test lines, the test result is not valid. With an invalid result, it is recommended to repeat the test using a new, unopened device following the instructions.

**Reagents and Materials Provided**

Contents Name	Quantity (in a kit) – Multi kit	Description
Test device	10 each	Foil pouched test device. Blood lancet and sample tube are mounted in plastic cassette.
Alcohol wipe	10 each	Individually pouched alcohol wipe.
Assay buffer vial	10 each	Na <sub>2</sub> CO <sub>3</sub> , < 0.1% sodium azide as a preservative.
Transfer pipette	10 each	For external control transfer.
Package insert	1 each	Instructions for use
Quick reference instructions	1 each	Quick reference instructions

## \* Materials required but not supplied

- Micropipette
- Timer
- Pair of gloves
- Tissue or wipe
- External positive and negative controls (available for purchase separately)

**Warnings and Precautions**

- For prescription and *in vitro* diagnostic use only. For Use under an Emergency Use Authorization Only.
- 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 has been authorized only for detecting the presence of IgM and 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.
- Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform high or moderate complexity tests.

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- Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This product is also authorized for use with fingerstick whole blood specimens at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Use immediately after removing the test device from the pouch.
- Immediately add the assay buffer to the test device after the specimen is applied.
- In order to obtain accurate results, the testing must follow instructions in this package insert.
- Do not interpret the test result before 15 minutes and after 20 minutes following the addition of buffer to the sample well.
- Do not use if the test device package is damaged.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Nitrile or latex gloves should be worn when performing this test.
- If the assay buffer contacts the skin or eye, flush with copious amounts of water.
- Handle all specimens as though they contain infectious agents.
- Adding additional blood sample volume to the sample well may cause false positive or invalid results.
- Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces a very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.

**Storage and Stability**

- Store the test kit as packaged between 1 ~ 30°C.
- The reagents and materials in the *CareStart™* EZ COVID-19 IgM/IgG are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.
- The test device must remain in the sealed pouch until use.
- Do not freeze any contents of the kit.

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IgM/IgG antibodies to SARS-CoV-2**Quality Control**

**Internal Quality Control:** The *CareStart™* EZ COVID-19 IgM/IgG contains a built-in internal procedural control in the test device. A red-colored line appearing in the control region “C” is designed as an internal procedural control. The appearance of the procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. If the procedural control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the manufacturer or distributor.

**External Control:** It is recommended to follow the laboratory regulations or quality control procedures to perform external controls in *CareStart™* EZ COVID-19 IgM/IgG. Controls are available through Access Bio under catalog number: SCLM-02571 or SCLM-10071.

**NOTE:** The external controls are available for separate purchase.

- Positive External Control: Mixture of human chimeric SARS-CoV-2 IgM and IgG spike S1 antibodies in heat-inactivated SARS-CoV-2 antibody-negative confirmed serum.
- Negative External control: Heat inactivated SARS-CoV-2 antibody-negative confirmed serum.

**External control testing procedures:**

1. Open a control vial containing the control reagents.
2. Transfer the control solution from the control vial:
  - a) *using a transfer pipette provided in the test kit:*  
Press the top part of the transfer pipette and touch the control solution by the pipette tip while pressing the pipette. Releasing the press slowly to fill the pipette with sample up to the blue marked line (approximately 10 µl). Add the control sample to the sample well of the test device by pressing the top part of the transfer pipette.
  - b) *using a micropipette:*  
Transfer 10 µl of the control solution to the sample well of the test device using a micropipette.
3. Twist off the tip of the assay buffer vial to open and add four (4) drops to the sample well immediately after sample loading.
4. Start a timer. Read the result at 15 minutes. The test results should not be read earlier than 15 minutes. The test results should not be read after 20 minutes.
5. Reseal the control vials and store them in their original container at 2 ~ 8°C.

**CareStart™ EZ COVID-19 IgM/IgG**Rapid diagnostic test for detection of  
IgM/IgG antibodies to SARS-CoV-2Expected Results of External Control:

**− Negative Control**      **+ Positive Control**

**NOTES:**  
If the test result for either the Negative Control or the Positive Control is not as expected, the test should be repeated using a new Test Device. If the test result for any of the controls is not as expected upon retesting, contact Technical Support.

**Specimen Type**

Acceptable specimen types for testing with the *CareStart™* EZ COVID-19 IgM/IgG are human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood. Proper specimen collection methods must be followed. Inadequate specimen collection and/or improper specimen handling may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

**Specimen Collection and Handling Procedures****Procedural Notes**

1. The *CareStart™* EZ COVID-19 IgM/IgG can be performed using human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood.
2. Allow test devices, reagents, and specimens to equilibrate up to room temperature (15~30°C) prior to testing.
3. Remove the *CareStart™* COVID-19 IgM/IgG test device from its foil pouch immediately before testing.

**• Fingerstick Whole Blood**

1. Collect the specimen wearing safety gloves to avoid contact and contamination.
2. Prick the middle or ring finger using the blood lancet encased in the test device following the testing instructions to draw fingerstick whole blood.
3. Process the fingerstick sample immediately after collection.
4. Use only the sample tube attached on the test device or micropipette for sample loading to the test device.

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- 5- Testing should be performed immediately after specimen collection.

# CareStart™ EZ COVID-19 IgM/IgG

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## [Test procedures for fingerstick whole blood sample]

**1** Prepare the **components** for the test.

**IMPORTANT:** Check expiration date before opening the foil pouch. Do not open the foil package until you have read the instructions and are ready to take the test. Use immediately upon opening.

Test device

- Tissue or wipe
- Timer
- Assay buffer vial
- Alcohol wipe

**2** Individual should **wash and dry** hands. **Clean** the fingertip to be pierced with an **alcohol wipe** and allow it **dry**.

**3** **Massage** to warm the finger for **5 to 10 seconds**.

**4** Gently **turn and pull** the **green sterility tab** out, then discard it.

**5** **Push hard** the **grey button** firmly by the finger to prick.

**Push hard** ←

**IMPORTANT**  
It only pricks once.

**6** Place the test device on the QRI.

**7** Hold the test device and **fill** the **sample tube** by touching the tip of sample tube with pricked finger.

**Sample tube**

Touch the tip of sample tube

**IMPORTANT**  
If having difficulty, wipe the finger and try again.

**Half full** ❌

**Full** ✅

**IMPORTANT**  
Sample tube must be full

**8** Hold the test device and **flip** the **sample tube** over all the way to the sample well. Make sure blood has transferred into the sample well.

**Flip**

**IMPORTANT**  
If blood has not transferred into the sample well, discontinue the test and retest with another device.

**9** **Twist** off the **tip** of assay buffer vial to open.

**Twist**

**10** Add **4 drops** in the sample well.

**IMPORTANT**  
**4 drops**

**11** Start a timer. **Read** the result at **15 minutes**. The test result should not be read after 20 minutes.

**IMPORTANT**

**15 mins**

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- **Venous Whole Blood**

Draw venous whole blood following the general laboratory procedures by a trained operator. Collect the blood sample in a commercially available blood collection tube containing anticoagulants including sodium citrate, sodium heparin, or dipotassium EDTA. Swirl the tube gently as needed.

- **Serum:**

Collect venous whole blood into a container NOT containing anticoagulants. Wait for the blood clot and separate the serum by centrifugation.

- **Plasma:**

Collect venous whole blood into a container containing anticoagulants (sodium citrate, sodium heparin, or dipotassium EDTA). Separate the plasma by centrifugation.

## **Test Procedures**

### **Procedural Notes**



- Use only the sample tube attached on the test device and transfer pipette or micropipette for sample loading to the test device.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the serum and plasma specimens at room temperature beyond 8 hours. Serum and plasma specimens may be stored at 2-8°C for up to 48 hours. For long term storage, serum and plasma specimens should be kept below -20°C for up to one month. It is recommended to test whole blood specimens immediately after blood collection.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens cannot be frozen and thawed more than once.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## CareStart™ EZ COVID-19 IgM/IgG

Rapid diagnostic test for detection of IgM/IgG antibodies to SARS-CoV-2

**[Test procedures for venous whole blood, serum, or plasma sample]**

**1** Prepare the **components** for the test.

**IMPORTANT:** Check expiration date before opening the foil pouch. Do not open the foil package until you have read the instructions and are ready to take the test. Use immediately upon opening.

Result window  
Sample well  
Sample tube  
Grey button  
Green sterility tab  
Test device

Tissue or wipe  
Timer  
Assay buffer vial  
Micro pipette

**2** Gently **turn** and **pull** the green sterility tab **out**, then discard it.

Turn first  
Then pull out

**3** Push the **grey button** firmly against the hard flat surface to **retract** the lancet.

Push hard

**4** Hold the test device and **fill** the **sample tube** with **10µl** of venous whole blood, serum or plasma using a **micro pipette**. If the sample tube isn't full, add more sample.

Sample tube  
Touch the tip of sample tube

**IMPORTANT**  
Ensure the sample tube is full before proceeding

**Half full**  
**Full**  
**IMPORTANT**  
Sample tube must be full

**5** Hold the test device and **flip** the **sample tube** over to the sample well. Make sure blood has transferred into the sample well.

Flip

**IMPORTANT**  
If blood has not transferred into the sample well, discontinue the test and retest with another device.

**6** **Twist** off the **tip** of assay buffer vial to open.

Twist

**7** Add **4 drops** in the sample well.

**IMPORTANT**  
4 drops

**8** Start a timer. **Read** the result at **15 minutes**. The test result should not be read after 20 minutes.

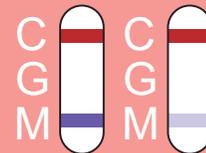
**IMPORTANT**  
15 mins

**CareStart™ EZ COVID-19 IgM/IgG**Rapid diagnostic test for detection of  
IgM/IgG antibodies to SARS-CoV-2**Interpretation of Results**

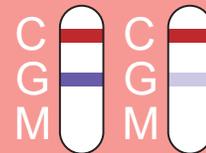
**NOTE:** The test results should be read and interpreted at 15 minutes after the sample application and the reading and interpretation of the results should not exceed 20 minutes. The test results should not be interpreted using any instruments.

**+ Positive****IgM Positive: Two distinct lines appear.**

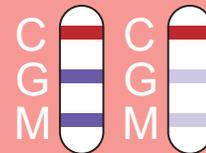
One red-colored line next to “C” and one purple-colored line next to “M” indicates a SARS-CoV-2 IgM positive result.

**IgG Positive: Two distinct lines appear.**

One red-colored line next to “C” and one purple-colored line next to “G” indicates a SARS-CoV-2 IgG positive result.

**IgM/IgG Positive: Three distinct lines appear.**

One red-colored line next to “C”, one purple-colored line next to “M”, and one purple-colored line next to “G” indicates a SARS-CoV-2 IgM and IgG positive result.

**Result with faint colored line(s):**

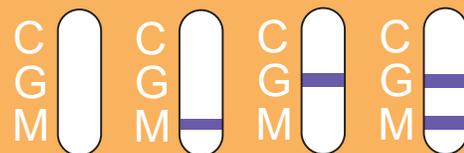
The color intensity in the test region will vary. Any faint colored line(s) in the test region(s) should be considered as positive.

**- Negative**

Only one line next to “C” indicates a negative result.

**? Invalid**

If the control line “C” is not visible, the result is invalid. Re-run the test using a new test device. If the same invalid result persists, contact the manufacturer or distributor before continuing the test.



**CareStart™ EZ COVID-19 IgM/IgG**Rapid diagnostic test for detection of  
IgM/IgG antibodies to SARS-CoV-2**Limitations**

1. Use of the *CareStart™* EZ COVID-19 IgM/IgG is limited to laboratory personnel who have been trained. Not for home use.
2. The test is limited to the qualitative detection of anti-COVID-19 antibody in human serum and plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood samples and does not indicate the quantity of the antibodies. The intensity of the test line does not necessarily correlate to the SARS-CoV-2 antibody titer in the specimen.
3. The test results should be interpreted 15 minutes after starting the test. The test results should not be interpreted after 20 minutes.
4. This test can only be used for the analysis of human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood samples.
5. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first several days of infection; the sensitivity of the Rapid COVID-19 IgM/IgG Combo Test Kit early after an infection is unknown. False-positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
6. 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.
7. The test may have lower sensitivity for IgG and IgM detection in symptomatic individuals prior to 15 days since symptom onset.
8. Direct testing with a molecular diagnostic test should be performed to evaluate for acute SARS-CoV-2 infection in symptomatic individuals.
9. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to determine infection status.
10. It is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.
11. Positive results 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 adaptive 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.
12. This test will only indicate the presence of SARS-CoV-2 IgM and/or IgG antibodies in the specimen.
13. The detection of SARS-CoV-2 IgM/IgG antibodies is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.

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14. This device has been evaluated for use with human specimen material only.
15. This test cannot rule out diseases caused by other bacterial or viral pathogens.
16. This device should not be used for the screening of donated blood.
17. 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 result from this assay should not be interpreted as an indication or degree of protection from infection after vaccination.
18. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected from March 27, 2020 to June 2, 2020 from multiple sites in the US (PA, ME, KS, CA, NJ, MA, and WA). The clinical performance characteristics of the *CareStart™* EZ COVID-19 IgM/IgG test for POC testing was evaluated in a multi-site prospective study in the U.S (California and New Mexico). 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 Laboratories**

The *CareStart™* EZ COVID-19 IgM/IgG Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and other 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>

Authorized Laboratories using the *CareStart™* EZ COVID-19 IgM/IgG must adhere to the Conditions of Authorization indicated in the Letter of Authorization are listed below:

1. Authorized laboratories using *CareStart™* EZ COVID-19 IgM/IgG must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories must use *CareStart™* EZ COVID-19 IgM/IgG as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized

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clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use *CareStart™* EZ COVID-19 IgM/IgG are not permitted.

3. Authorized laboratories that receive *CareStart™* EZ COVID-19 IgM/IgG must notify the relevant public health authorities of their intent to run *CareStart™* EZ COVID-19 IgM/IgG prior to initiating testing.

4. Authorized laboratories using *CareStart™* EZ COVID-19 IgM/IgG 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 *CareStart™* EZ COVID-19 IgM/IgG and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Access Bio, Inc. Technical Support (TShelp@accessbio.net) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of *CareStart™* EZ COVID-19 IgM/IgG of which they become aware.

6. All laboratory personnel using *CareStart™* EZ COVID-19 IgM/IgG must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use *CareStart™* EZ COVID-19 IgM/IgG 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 *CareStart™* EZ COVID-19 IgM/IgG.

7. Access Bio, Inc., authorized distributors, and authorized laboratories using *CareStart™* EZ COVID-19 IgM/IgG 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.

<sup>a</sup> The letter of authorization refers to, "authorized laboratories" as the following:

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Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

**Performance Characteristics****Clinical Agreement****Study I: Retrospective Study – Serum**

The clinical performance of the *CareStart™* EZ COVID-19 IgM/IgG was evaluated using retrospectively collected SARS-CoV-2 serum samples by 3 operators at a US site. A total of 106 serum samples (31 positives and 75 pre-COVID negatives) were tested in this study. 75 pre-COVID negatives samples were collected in the US before December 2019. All the collected positive serum samples were confirmed by FDA-authorized SARS-CoV-2 RT-PCR tests as comparators.

All the negative and positive samples were tested in a blinded fashion. Each sample was assigned with a unique subject identification code during collection and randomized prior to the testing. The expected results of the samples were completely blinded to the operators in this study. All the samples were tested according to the *CareStart™* EZ COVID-19 IgM/IgG testing procedures.

A total of 106 samples were considered evaluable in this study.

***CareStart™* EZ COVID-19 IgM/IgG Performance against the Comparator Methods - Serum**

For IgG antibody detection, the positive percent agreement (PPA) of *CareStart™* EZ COVID-19 IgM/IgG was 96.8% (30/31) (95% CI of 83.8–99.4%). For IgM antibody detection, the PPA was 100% (31/31) (95% CI of 89.0–100%). The overall NPA (either IgG positive or IgM positive counted as positive) was 100% (75/75) (95% CI 95.1 – 100%).

**IgM/IgG PPA results stratified by days post-onset of symptoms – serum**

Days from Symptom Onset	No. of RT-PCR Positive	IgM Positive	IgM PPA	95% CI	IgG Positive	IgG PPA	95% CI
0 – 7 days	0	0	NA	NA	0	NA	NA
8 – 14 days	3	3	100%	43.9 – 100.0%	2	66.7%	20.8 – 93.9%
≥15 days	28	28	100%	87.9 – 100.0%	28	100%	87.9 – 100%

**CareStart™ EZ COVID-19 IgM/IgG**

Rapid diagnostic test for detection of IgM/IgG antibodies to SARS-CoV-2

Total	31	31	N/A	N/A	30	N/A	N/A
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Study II: Independent Clinical Agreement Validation

The *CareStart™* EZ COVID-19 IgM/IgG from Access Bio, Inc. was tested on May 4, 2021 at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Cancer Institute (NCI). The test was evaluated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative plasma (ACD) samples. Each of the 30 antibody-positive samples was confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the *CareStart EZ* COVID-19 IgM/IgG. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include: i) Seventy (70) samples selected without regard to clinical status, “Negatives” and ii) Ten (10) samples selected from banked serum from HIV+ patients, “HIV+”. Testing was performed by one operator using one lot of the *CareStart™* COVID-19 IgM/IgG. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody negative samples with HIV was statistically higher than the false positive rate among antibody negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman.)

The results and data analysis are shown in the tables below:

	Comparator Method			Collected pre-2020		Total
	Antibody Positive			Antibody Negative		
<i>CareStart EZ</i> COVID-19 IgM/IgG	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	
IgM+, IgG+	25					25
IgM+, IgG-	1					1
IgM-, IgG+	4					4
IgM-, IgG-				70	10	80
<b>Total</b>	30			70	10	110

**CareStart™ EZ COVID-19 IgM/IgG**

Rapid diagnostic test for detection of IgM/IgG antibodies to SARS-CoV-2

Measure	Estimate	Confidence Interval
IgM Sensitivity	86.7% (26/30)	70.3%; 94.7%
IgM Specificity	100% (80/80)	95.4%; 100%
IgG Sensitivity	96.7% (29/30)	83.3%; 99.4%
IgG Specificity	100% (79/80)	95.4%; 100%
Combined Sensitivity	100% (30/30)	88.7%; 100%
Combined Specificity	100% (80/80)	95.4%; 100%
Combined PPV for prevalence = 5.0%	100%	50.5%; 100%
Combined NPV for prevalence = 5.0%	100%	99.4%; 100%
Cross-reactivity with HIV+	0.0% (0/10), not detected	-

Important limitations of the study:

1. Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real world performance of the device
2. These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
3. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

### Study III: Prospective Fingertick Study (POC)

The clinical performance characteristics of the *CareStart™* EZ COVID-19 IgM/IgG test was evaluated in a multi-site prospective study in the U.S. against an FDA authorized RT-PCR molecular assay as a comparator method. A total of two (2) Point-of-Care investigational sites in the U.S. (California and New Mexico) participated in the study. To be enrolled in the study, the positive patients had to be confirmed as positive by an FDA authorized RT-PCR and exhibit signs/symptoms of the COVID-19-like illness within 5 to 28 days prior to testing with the devices under evaluation. The negative subjects had to be confirmed as negative by an FDA authorized RT-PCR and currently present no signs or onset of symptoms and no previous infection history.

Testing was performed by eight (8) operators with no laboratory experience and who were representative of the intended users. Operators only used the QRI for the test without any training provided and completed an ease-of-use questionnaire indicating favorable responses to all questions asked after completing the study.

A total of 77 specimens were evaluable. The performance of the *CareStart™* EZ COVID-19 IgM/IgG test compared to the comparator method is presented in the tables below.

**CareStart™ EZ COVID-19 IgM/IgG**

Rapid diagnostic test for detection of IgM/IgG antibodies to SARS-CoV-2

IgM/IgG PPA results stratified by days post symptoms onset – fingerstick

Days from Symptom Onset	No. of RT-PCR Positive	IgM Positive	IgM PPA	95% CI	IgG Positive	IgG PPA	95% CI
0 – 7 days	1	1	100%	20.7 – 100%	1	100%	20.7 – 100%
8 – 14 days	17	17	100%	81.6 – 100%	16	94.1%	73.0 – 99.0%
≥15 days	16	16	100%	80.6 – 100%	16	100%	80.6 – 100%
Total	34	34	<b>N/A</b>	N/A	33	N/A	N/A

The NPA of the *CareStart* EZ COVID-19 IgG/IgM Rapid Test Device for IgG/IgM in fingerstick whole blood samples is 100% (43/43) (95% CI 91.8 – 100.0%).

**Cross-Reactivity (Exclusivity)**

The cross-reactivity study was conducted by testing a total of 80 plasma or serum samples, including 15 non-SARS-CoV-2 pathogens and one (1) autoantibody. All the plasma and serum samples tested as negative showed no cross-reactivity and resulted in 100% agreement between *CareStart*™ EZ COVID-19 IgM/IgG test result and the expected result as presented in the table below:

Samples	Sample number and type	Test results (# of positive / # of replicate)	
		IgM Results	IgG Results
Anti-Influenza A	5 plasma	0/5	0/5
Anti-Influenza B	5 plasma	0/5	0/5
Anti-HCV	5 serum	0/5	0/5
Anti-HBV	5 serum	0/5	0/5
Anti-229E (alpha coronavirus)	5 plasma	0/5	0/5
Anti-NL63 (alpha coronavirus)	5 plasma	0/5	0/5
Anti-OC43 (beta coronavirus)	5 plasma	0/5	0/5
Anti-HKU1 (beta coronavirus)	5 plasma	0/5	0/5
Anti-SARS-CoV	5 plasma	0/5	0/5
Anti-MERS	5 plasma	0/5	0/5
Antinuclear antibodies (ANA)	5 serum	0/5	0/5
Anti-respiratory syncytial virus	5 serum	0/5	0/5
Anti-HIV	5 plasma	0/5	0/5
Anti-Dengue virus	5 plasma	0/5	0/5
Anti- <i>T. pallidum</i> (Syphilis)	5 serum	0/5	0/5
Anti-Haemophilus influenzae	5 plasma	0/5	0/5

**Interfering Substances**

**CareStart™ EZ COVID-19 IgM/IgG**

Rapid diagnostic test for detection of IgM/IgG antibodies to SARS-CoV-2

To assess substances with the potential to interfere with the performance of the *CareStart™* EZ COVID-19 IgM/IgG, SARS-CoV-2 IgM, IgG positive, and negative samples were tested with the addition of potentially interfering substances. The *CareStart™* EZ COVID-19 IgM/IgG test performance was not affected by any of the eight potentially interfering substances tested.

- Acetaminophen
- Acetylsalicylic acid
- Albendazole
- Chloroquine diphosphate
- HAMA
- Hemoglobin
- Ibuprofen
- Rifampicin

The interfering effects of biotin concentrations ranging between 10 ng/ml and 100 µg/ml were tested in a separate study. Biotin concentrations up to 2.5 µg/ml did not lead to false results. Biotin concentrations, 5 µg/ml and above can cause false-negative IgM results with the *CareStart™* EZ COVID-19 IgM/IgG. None of the IgG positive samples tested produced false negative in all biotin concentrations tested.

**Class Specificity**

The *CareStart™* EZ COVID-19 IgM/IgG was evaluated to determine that the assay accurately detects each SARS-CoV-2 IgM and IgG antibody class on its corresponding test lines. A total of five (5) IgM and IgG positive serum samples were treated with dithiothreitol (DTT) to determine the class specificity of the test. All samples treated with DTT showed no visible IgM line with the *CareStart™* EZ COVID-19 IgM/IgG, whereas the IgG results were not affected by DTT treatment. IgM and IgG results after DTT treatment showed 100% agreement to the expected results.

**Matrix Equivalency**

The matrix equivalency study was performed by spiking SARS-CoV-2 IgM/IgG positive sample into negative sample matrices for serum, venous whole blood, and plasma using different anticoagulants. All testing matrices were collected from the same donor and a total of five donors were evaluated in *CareStart™* EZ COVID-19 IgM/IgG. The venous whole blood samples were collected from each individual in four different containers to prepare serum (no anticoagulant), and three matrices each of venous whole blood (sodium citrate, sodium heparin, and dipotassium EDTA) and plasma (sodium citrate, sodium heparin, and dipotassium EDTA). To prepare positive sample panels, each sample matrix was spiked with SARS-CoV-2 IgM/IgG positive serum sample at low positive and moderate positive levels and randomized for testing. The samples were tested in duplicate with the *CareStart™* EZ COVID-19 IgM/IgG. All the test results of seven different matrices from the individual showed 100% agreement to the expected results.

Sample type	Test results (# of positive / # of replicate (% agreement))
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**CareStart™ EZ COVID-19 IgM/IgG**Rapid diagnostic test for detection of  
IgM/IgG antibodies to SARS-CoV-2

	LP results		MP results		Negative results	
	IgM	IgG	IgM	IgG	IgM	IgG
Venous whole blood (EDTA)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	0/10 (100%)	0/10 (100%)
Venous whole blood (Heparin)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	0/10 (100%)	0/10 (100%)
Venous whole blood (Citrate)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	0/10 (100%)	0/10 (100%)
Plasma (EDTA)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	0/10 (100%)	0/10 (100%)
Plasma (Heparin)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	0/10 (100%)	0/10 (100%)
Plasma (Citrate)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	0/10 (100%)	0/10 (100%)
Serum	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	0/10 (100%)	0/10 (100%)

**Technical Support**

For questions, or to report a problem, please call Technical Support at +1-888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available).

**Description of Symbols**

**CareStart™ EZ COVID-19 IgM/IgG**Rapid diagnostic test for detection of  
IgM/IgG antibodies to SARS-CoV-2

## Symbol Descriptions



**IVD** *In vitro* diagnostic medical device  
Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.



**Consult instructions for use**  
Indicates the need for the user to consult the instructions for use.



**Manufacturer**  
Indicates the medical device manufacturer.



**LOT** Batch code  
Indicates the manufacturer's batch code so that the batch or lot can be identified.



**Do not re-use**  
Indicates a medical device that is intended for one use, or uses on a single patient during a single procedure.



**Use by date**  
Indicates the date after which the medical device is not to be used.



**Prescription-only**



**Manufacturer:**  
**ACCESS BIO, INC.**  
65 Clyde Road, Suite A. Somerset, NJ 08873, USA  
Tel: 732-873-4040  
Fax: 732-873-4043  
Email: [info@accessbio.net](mailto:info@accessbio.net)  
Website: [www.accessbio.net](http://www.accessbio.net)

## Symbol Descriptions



**REF** Catalog number  
Indicates the manufacturer's catalog number so that the medical device can be identified.



**Caution**  
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



**Date of manufacture**  
Indicates the date when the medical device was manufactured.



**Temperature limit**  
Indicates the temperature limits to which the medical device can be safely exposed.



**Do not use if the package is damaged**  
Indicates a medical device that should not be used if the package has been damaged or opened.



**Contains sufficient for <n> tests**  
Indicates the total number of IVD tests that can be performed with the IVD.

**Technical Support in the U.S.**  
Tel: +1-888-898-1270 (Toll Free)  
Email: [TShelp@accessbio.net](mailto:TShelp@accessbio.net)

Document number: IFU-RCKM72-E  
Revision number: A  
Effective date: 2021-06-15

# Quick Reference Instructions (QRI) for CareStart™ EZ COVID-19 IgM/IgG

Rapid test for the detection of IgM/IgG antibodies to SARS-CoV-2

For use under Emergency Use Authorization Only  
 For Prescription Use only  
 For *In Vitro* Diagnostic Use Only

**Important Note:**

- Test should not be used beyond its expiration date.
- Read the complete Quick Reference Instructions before performing the test for fingerstick whole blood.
- Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG and IgM assay.
- Refer to the package insert for specimen collection and handling for venous whole blood serum, or plasma.



## Test Procedures for Fingerstick Whole Blood Sample

**1** Prepare the **components** for the test.

**IMPORTANT:** Check expiration date before opening the foil pouch. Do not open the foil package until you have read the instructions and are ready to take the test. Use immediately upon opening.

- Tissue or wipe
- Timer
- Assay buffer vial
- Alcohol wipe

**2** Individual should **wash and dry** hands. **Clean** the fingertip to be pierced with an **alcohol wipe** and allow it **dry**.

**3** **Massage** to warm the finger for **5 to 10 seconds**.

**4** Gently **turn and pull** the **green sterility tab** out, then discard it.

**5** **Push hard** the **grey button** firmly by the finger to prick.

**IMPORTANT** It only pricks once.

**6** Place the test device on the QRI.

**7** Hold the test device and **fill the sample tube** by touching the tip of sample tube with pricked finger.

**IMPORTANT** If having difficulty, wipe the finger and try again.

**Half full** (Incorrect)

**Full** (Correct)

**IMPORTANT** Sample tube must be full

**8** Hold the test device and **flip the sample tube** over all the way to the sample well. Make sure blood has transferred into the sample well.

**IMPORTANT** If blood has not transferred into the sample well, discontinue the test and retest with another device.

**9** **Twist** off the **tip** of assay buffer vial to open.

**10** Add **4 drops** in the sample well.

**IMPORTANT** 4 drops

**11** Start a timer. **Read the result at 15 minutes.** The test result should not be read after 20 minutes.

**IMPORTANT** 15 mins

### Results Interpretation

- Make sure you wait the full 15 minutes.
- If individual's finger is still bleeding use a tissue or wipe.

**- Negative**  
 Only one line next to "C" indicates a negative result.

**? Invalid**  
 If the control line "C" is not visible, the result is invalid.

**NOTES:**  
 - Re-run the test using a new test device.

**+ Positive**  
 Two or three distinct lines including control line indicates a positive result.

**IgM Positive**      **IgG Positive**      **IgM, IgG Positive**

**NOTES:**  
 - The color intensity in the test region will vary.  
 - Any faint colored line(s) in the test region(s) should be considered as positive.



In the USA, 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 has been authorized only for detecting the presence of IgM and 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.

### External Control Testing Procedures

User should refer to the instructions for use for the external control testing.

1. Open a control vial containing the control reagents.
2. Transfer the control solution from the control vial:
  - a) using a transfer pipette provided in the test kit: Press the top part of the transfer pipette and touch the control solution by the pipette tip while pressing the pipette. Releasing the press slowly to fill the pipette with sample up to the blue marked line (approximately 10 µL). Add the control sample to the sample well of the test device by pressing the top part of the transfer pipette.
  - b) using a micropipette: Transfer 10 µL of the control solution to the sample well of the test device using a micropipette.
3. Twist off the tip of the assay buffer vial to open and add four (4) drops to the sample well immediately after sample loading.
4. Start a timer. Read the result at 15 minutes. The test results should not be read earlier than 15 minutes. Test results should not be read after 20 minutes.
5. Reseal the control vials and store them in their original container at 2 - 8°C.

**Expected Results:**

**- Negative Control**      **+ Positive Control**

**NOTES:**  
 If the test result for either the Negative Control or the Positive Control is not as expected, the test should be repeated using a new Test Device. If the test result for any of the controls is not as expected upon retesting, contact Technical Support.

**Access Bio, Inc.**  
 65 Clyde Road, Suite A  
 Somerset, NJ 08873, USA  
 Tel: 732-873-4040  
 Fax: 732-873-4043  
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 Website: www.accessbio.net

**Technical Support**  
 Tel: 888-898-1270 (Toll Free)  
 Email: TShelp@accessbio.net

**QRI-RCKM-E / 2021-06-15**



**For use under Emergency Use Authorization only  
For prescription use only  
For *in vitro* diagnostic use only**

**CareStart™**  
**COVID-19**  
**Antibody External Controls**

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**Package Insert  
(Instructions for Use)**

# CareStart™ COVID-19 Antibody External Controls

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## CareStart™ COVID-19 Antibody External Controls

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**For use under Emergency Use Authorization only**  
**For *in vitro* diagnostic use only**  
**For prescription use only**

### Intended Use

*CareStart*™ COVID-19 Antibody External Controls are intended to be used for *in vitro* diagnostic use in the quality control of the *CareStart*™ COVID-19 IgM/IgG, Rapid Response™ Liberty COVID-19 IgG/IgM, and *CareStart*™ EZ COVID-19 IgM/IgG tests.

**For *in vitro* diagnostic use.**

### When to use

Run the Controls under the following circumstances:

- when a new lot of the test kit is opened
- whenever a new shipment of test kits arrives
- for each new operator before testing
- if the temperature of the test storage area falls outside of the recommended storage conditions
- at periodic intervals as dictated by the user facility.

It is the responsibility of each laboratory using the *CareStart*™ COVID-19 IgM/IgG, Rapid Response™ Liberty COVID-19 IgG/IgM, or *CareStart*™ EZ COVID-19 IgM/IgG tests to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

### Summary and Explanation of the External Controls

*CareStart*™ COVID-19 Antibody External Controls consist of a Positive Control and a Negative Control. External Controls are used as quality control. The purpose of quality control is to ensure the proper performance of the test. The positive control is a mixture of human chimeric SARS-CoV-2 spike S1 reactive IgM and recombinant human SARS-CoV-2 spike S1 reactive IgG antibodies in heat-inactivated SARS-CoV-2 antibody-negative confirmed serum. Negative Control is heat-inactivated SARS-CoV-2 antibody-negative confirmed serum.

### Reagents and Materials Provided

Contents Name	Quantity (in a kit)	Description
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## CareStart™ COVID-19 Antibody External Controls

Positive Control	1 vial each	Mixture of human chimeric SARS-CoV-2 spike S1 reactive IgM and recombinant human SARS-CoV-2 spike S1 reactive IgG antibodies in heat-inactivated SARS-CoV-2 antibody-negative confirmed serum. < 0.1% sodium azide as a preservative.
Negative Control	1 vial each	Heat inactivated SARS-CoV-2 antibody-negative confirmed serum. < 0.1% sodium azide as a preservative.
Package insert	1 each	Instructions for use

\* Materials not supplied

- 20 µl Micropipette
- Timer
- Pair of gloves

### Warnings and Precautions

- For *in vitro* diagnostic use.
- For laboratory/ professional use only.
- For use under Emergency Use Authorization only.
- 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 IgM and IgG antibodies to SARS-CoV2, 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.
- **CareStart™ COVID-19 Antibody External Controls** are only available for use with the **CareStart™ COVID-19 IgM/IgG, Rapid Response™ Liberty COVID-19 IgG/IgM, and CareStart™ EZ COVID-19 IgM/IgG tests.**
- This control is provided for quality assurance only and must not be used for calibration.
- Read this package insert and the test kit package insert completely before using these controls. In order to obtain accurate results, the test must follow this package insert. Handle the External Controls as though they are capable of transmitting infectious agents.
- Do not eat, drink, or smoke in the area where the external controls are handled.
- Nitrile or latex gloves should be worn when performing this test.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Wipe all spills thoroughly with a freshly prepared solution of 10% bleach or other appropriate disinfectants.
- Use of the control reagents manufactured by any other sources may not produce the required results, and therefore, will not meet the requirements for an adequate quality

## CareStart™ COVID-19 Antibody External Controls

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assurance program for the CareStart™ COVID-19 IgM/IgG, Rapid Response™ Liberty COVID-19 IgG/IgM, and CareStart™ EZ COVID-19 IgM/IgG tests.

- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

### Storage and Stability

- Store the External Controls as packaged between 2 - 8°C.
- The External Controls are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.
- Open the External Control vials only when performing tests.
- Recap and store the External Control vials in their original package at 2 - 8°C after use.

### Test Procedures

#### Procedural Notes

- Perform test procedures as indicated in the CareStart™ COVID-19 IgM/IgG, Rapid Response™ Liberty COVID-19 IgG/IgM, and CareStart™ EZ COVID-19 IgM/IgG package inserts.

#### Test Procedures: CareStart™ COVID-19 IgM/IgG

1. Open a control vial containing the control reagents.
2. Transfer the control solution from the control vial:
  - a) *using a transfer pipette provided in the test kit:*

Press the top part of the transfer pipette and touch the control solution by the pipette tip while pressing the pipette. Releasing the press slowly to fill the pipette with sample up to the blue marked line (approximately 10 µl). Add the control sample to the sample well “S” of the test device by pressing the top part of the transfer pipette.
  - b) *using a micropipette:*

Transfer 10 µl of the control solution to the sample well “S” of the test device using a micropipette.
3. Open the cap and invert the assay buffer bottle and hold vertically above the sample well. Squeeze the bottle gently to add one (1) drop of the assay buffer solution to the sample well “S” immediately after sample loading.
4. Start a timer. Read the result at 10 minutes. The test results should not be read earlier than

## CareStart™ COVID-19 Antibody External Controls

10 minutes. Test results should not be read after 15 minutes.

5. Reseal the control vials and store them in their original container at 2 ~ 8°C.

### **Test Procedures: CareStart™ EZ COVID-19 IgM/IgG**

1. Gently turn and pull the green sterility tab out, then discard it.
2. Push the grey button firmly against the hard flat surface to retract the lancet.
3. Place the test device on the QRI.
4. Open a control vial containing the control solutions.
5. Transfer the control solution from the control vial:
  - a) *using a transfer pipette provided in the test kit:*

Press the top part of the transfer pipette and touch the control solution by the pipette tip while pressing the pipette. Releasing the press slowly to fill the pipette with sample up to the blue marked line (approximately 10 µl). Add the control sample to the sample well of the test device by pressing the top part of the transfer pipette.
  - b) *using a micropipette:*

Transfer 10 µl of the control solution to the sample well of the test device using a micropipette.
6. Twist off the tip of assay buffer vial to open.
7. Add 4 drops in the sample well.
8. Start a timer. Read the result at 15 minutes. The test result should not be read after 20 minutes.

### Expected Results

#### **Positive Control: three distinct lines appear.**

One red-colored line next to “C”, one purple-colored line next to “M”, and one purple-colored line next to “G” indicates SARS-CoV-2 IgM and IgG positive result.



## CareStart™ COVID-19 Antibody External Controls

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**Negative Control: one distinct line appears.**

Only one red-colored line next to “C” indicates a negative result.



**NOTE:** If the test result for either the Negative Control or the Positive Control is not as expected, the test should be repeated using a new Test Device. If the test result for any of the controls is not as expected upon retesting, contact Technical Support.

### Technical Support

For questions, or to report a problem, please call Technical Support at +1-888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or [TShelp@accessbio.net](mailto:TShelp@accessbio.net) (24/7 available).

## CareStart™ COVID-19 Antibody External Controls

### Ordering Information

- SCLM-02571: CareStart™ COVID-19 Antibody External Controls, 25 Test
- SCLM-10071: CareStart™ COVID-19 Antibody External Controls, 100 Test

### Description of Symbols

Symbol	Descriptions	Symbol	Descriptions
	<b>In vitro</b> diagnostic medical device Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device.		<b>Catalog number</b> Indicates the manufacturer's catalog number so that the medical device can be identified.
	<b>Consult instructions for use</b> Indicates the need for the user to consult the instructions for use.		<b>Caution</b> Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	<b>Manufacturer</b> Indicates the medical device manufacturer.		<b>Use by date</b> Indicates the date after which the medical device is not to be used.
	<b>Batch code</b> Indicates the manufacturer's batch code so that the batch or lot can be identified.		<b>Temperature limit</b> Indicates the temperature limits to which the medical device can be safely exposed.
	<b>Contains sufficient for &lt;n&gt; tests</b> Indicates the total number of IVD tests that can be performed with the IVD.		



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