Summary and Explanation of the Test

For prescription and in vitro diagnostic use only.

The CareStart® COVID-19 Antigen test is a rapid lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are either suspected of COVID-19 by their healthcare provider within first five days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested two to three times during the first 24 to 36 hours of symptom onset. The test is intended to be interpreted visually in both laboratory and patient testing environments without an instrument.

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

For use under the Emergency Use Authorization (EUA) only

For use only

Instructions (QRI)

Negative control swab

Positive control swab

Extraction vial / cap

Antigen test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 - protein antigens specific to SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are suspected of COVID-19. The test is not recommended for use in patients with signs and symptoms who are suspected of COVID-19 because it can be taken from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested two to three times during the first 24 to 36 hours of symptom onset.

Reagents and Materials Provided

- Patient’s name
- Test device
- Positive control strip
- Negative control strip
- Quick Reference Instructions (QRI)

- Antigen test strip
- Extraction vial/cap
- Micropipette
- 1 each
- 1 each
- 1 each
- 1 each
- 1 each

Storage and Stability

- Store the test kit as packaged between 1~30°C.
- Do not re-use the test kit.
- Do not use the kit beyond the expiration date.

Quality Control

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- The test is intended to be interpreted visually in both laboratory and patient testing environments without an instrument.

Principles of the Test

The CareStart® COVID-19 Antigen test is a rapid lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2. The test contains a test strip, which is encased in plastic device cassette. The test strip contains an antigen capture antibody, which is dried on the foam-tipped head. The antigen test strip is contained in the pouch.

Test results are interpreted at 10 minutes. The presence of two colored lines in the control line region “C” and test line region “T” indicates COVID-19 positive. The presence of one colored line in the control line region “C” indicates COVID-19 negative. No appearance of a colored line in the control line region “C” indicates an invalid test result.
The CareStart™ COVID-19 Antigen test kit is for use only with a direct nasopharyngeal or anterior nasal swab specimen. Your product should not be used with other liquid samples such as nasal wash, aspirate samples or samples obtained from transport media as results can be compromised by other dilution.

Direct Swab Test Procedure

1. Peel off aluminum foil seal from cap and push firmly onto the vial.
2. Place the swab into the extraction solution containing at least 5 times the sample volume.
3. Place swab on the Pad and push firmly into the vial.
4. Remove the swab by rotating the extraction tube while squeezing the sides of the vial to release the liquid from the swab. Properly dispose the swab.
5. Mix thoroughly by flicking the bottom of the tube.
6. Insert the extraction tube and hold at room temperature for 10 minutes. The sample will fill into the sample collection vial. At the end of 10 minutes, invert the vial to mix the sample. For best results, gently mix the sample to fill into the sample collection vial. Do not shake the vial to initiate the test run and avoid introducing air bubbles into the vial as this may affect the test results.

Performance Characteristics

Clinical Performance – Nasopharyngeal Swab

The clinical performance characteristics of the CareStart™ COVID-19 Antigen test were established using a multi-site prospective study in the U.S. between November 2020 and December 2020. The study was conducted by 46 FDA-authorized FD/CLIA certified laboratory locations. The CareStart™ COVID-19 Antigen test was compared to a SARS-CoV-2 rRT-PCR test that had been performed within 5 days of symptom onset from the same specimen used for the COVID-19 Antigen test. The CareStart™ COVID-19 Antigen test was performed on 345 samples collected from COVID-19 positive patients. The cumulative rRT-PCR performed by FD/CLIA certified laboratories at the participating study sites was 100% sensitive and 95% specific (Sensitivity: 100.00%; Specificity: 95.00%; Positive Predicted Value: 86.4%, Negative Predicted Value: 99.7%). The network of FD/CLIA certified laboratories participating in the clinical performance study were anticipated to be reflective of the prevalent variants in circulation at the time of the study.

At least 50% of samples collected were from patients with fever and at least two of the following respiratory symptoms: cough, shortness of breath, or difficulty breathing. The remaining 50% of samples were collected from asymptomatic patients. The age distribution of participants was 33% age 17-49 years; 29% age 50-64 years; 18% age 65-74 years; 10% age 75-84 years; and 10% age > 85 years.

The clinical performance characteristics of the CareStart™ COVID-19 Antigen test were compared to the SARS-CoV-2 rRT-PCR test. False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking medications known to adversely affect test performance and/or invalidate the test result. The performance of the test may be affected by the presence of biotin concentrations ranging between 625 ng/mL and 2.5 µg/mL.

Analytical Sensitivity: Limit of Detection (LoD)

The LoD for direct swab was established using heat-inactivated SARS-CoV-2 rRT-PCR positive human nasopharyngeal swab to demonstrate the agreement with the comparator method. A total of 10 triplicates of 100,000 copies/mL SARS-CoV-2 were used to establish the LoD. Analytical Sensitivity Limit was determined using the 100,000 copies/mL SARS-CoV-2 rRT-PCR positive human nasopharyngeal swab spiked into the VTM at a concentration of 100 copies/mL.

The performance of this test has not yet been clinically validated for use in pregnant women or individuals with known sensitivity to any of the components of the test kit. False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking medications known to adversely affect test performance and/or invalidate the test result.

Clinical Performance – Anterior Nasal Swab

The clinical performance characteristics of the CareStart™ COVID-19 Antigen test were established on 430 nasopharyngeal or anterior nasal swabs from COVID-19 positive patients collected from multiple healthy volunteers eluted in VTM and confirmed as SARS-CoV-2 rRT-PCR positive at three independent clinical sites. The cumulative rRT-PCR performed by FD/CLIA certified laboratories at the participating study sites was 100% sensitive and 98% specific (Sensitivity: 100.00%; Specificity: 98.4%; Positive Predicted Value: 83.7%; Negative Predicted Value: 100.0%). The network of FD/CLIA certified laboratories participating in the clinical performance study were anticipated to be reflective of the prevalent variants in circulation at the time of the study. The clinical performance characteristics of the CareStart™ COVID-19 Antigen test were compared to the SARS-CoV-2 rRT-PCR test. False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking medications known to adversely affect test performance and/or invalidate the test result.

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Quick Reference Instructions for CareStart™ COVID-19 Antigen

For Emergency Use Authorization (EU) Only

The CareStart™ COVID-19 Antigen test is a lateral flow immunocromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are either suspected of COVID-19 by their healthcare provider within first five days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

IMPORTANT!
- Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
- Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information.
- Biomarker interference - False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (>10 mg per day). Biotin levels of 2.5 μg/mL have been demonstrated to result in false negative test results.
- The extracted sample must be used within 4 hours of preparation when stored at room temperature.

SPECIMEN COLLECTION AND HANDLING

Nasopharyngeal (NP) Swab Collection

1. Remove a nasopharyngeal swab from the pouch.
2. Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.
3. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.
4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

Anterior Nasal Swab Collection

1. Remove a nasal swab from the pouch.
2. Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.
3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab, repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.
4. Slowly remove the swab from the nostril while rotating it.
Quick Reference Instructions for CareStart™ COVID-19 Antigen

**TEST PROCEDURES**

1. Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.

2. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.

3. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.

4. Close the vial by pushing the cap firmly onto the vial.

5. Mix thoroughly by flicking the bottom of the tube.

6. Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.

   **NOTE:** Refer to the Package Insert for the cautions.

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**Result Interpretation**

- **Positive:** SARS-CoV-2 antigen present; does not rule out co-infection with other pathogens. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

- **Negative:** Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

- **Invalid:** If the red-colored line in the control region “C” is not visible, the result is invalid. Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.

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External Control Swab: It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the nasopharyngeal swab test procedure provided in this package insert or the quick reference instruction card.

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If used on asymptomatic individuals for serial testing, a second test should be performed with at least 24 hours (and no more than 48 hours) between tests. For serial testing, additional confirmatory testing with a molecular test for negative results may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as, an individual with a close contact or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of SARS-CoV-2 infection, such individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.