CareStart™

COVID-19 Antigen

A Rapid POC Test

Due to the highly contagious nature and global spread, SARS-CoV-2 has been designated as a pandemic by the World Health Organization (WHO) and continues to have devastating impacts on healthcare systems and the world economy including the U.S. To effectively end the SARS-CoV-2 pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical.

As an intended point-of-care (POC) designated test with a 10 minute processing time, CareStart™ COVID-19 Antigen Test allows effective screening of COVID-19 infection in symptomatic patients on a large scale.

FDA Authorized Under EUA

CE

Features

- Lateral flow assay
- Rapid results in 10 minutes
- Nasopharyngeal specimen collection
- Intended at POC setting (i.e., in patient care settings) by medical professionals with a CLIA waiver

Clinical Features

- Detect SARS-CoV-2 nucleocapsid protein antigen
- Identify acute infection with 88.4% sensitivity and 100% specificity
- Storage condition : 1-30 degrees celsius

The CareStartTM COVID-19 Antigen test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories and at the Point of Care by medical professionals operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only to detect the presence of the SARS-CoV-2 nucleocapsid protein antigen,, not for any other viruses or pathogens; this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

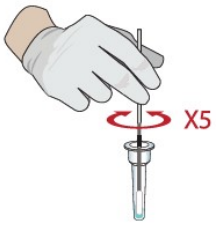
Test Principles

The CareStart™ COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in swab specimens directly collected from symptomatic individuals who are suspected of COVID-19 by their healthcare providers.

Procedure

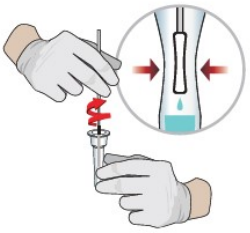
01

Peel off aluminum foil seal and rotate the swab inside the extraction vial vigorously at least 5 times.



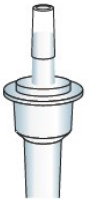
02

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.



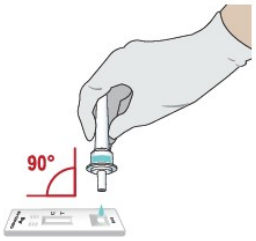
03

Close the vial by pushing the cap firmly onto the vial and mix thoroughly by flicking the bottom of the tube.



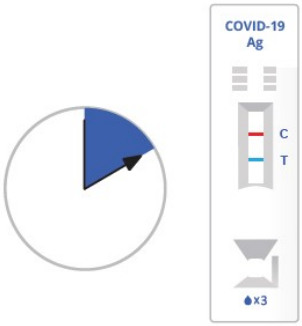
04

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.

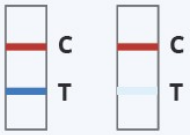


Results Interpretation

Read the result at 10 minutes. The test result should not be read after 15 minutes.



Positive

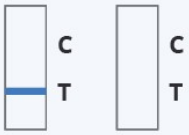


SARS-CoV-2 antigen present does not rule out co-infection with other pathogens. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

Negative

Negative 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. It is recommended that these results be conrmed by a molecular testing method, if necessary for patientmanagement.

Invalid



Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.

Order Information

Cat No.	RCHM-02071
Package Unit	20 tests/kit
Kit Component	20 Test devices 20 Assay buffer 20 Extraction vials and caps 20 Specimen collection swabs 1 Positive and 1 negative control swabs 1 Instructions for Use