

CareStart™

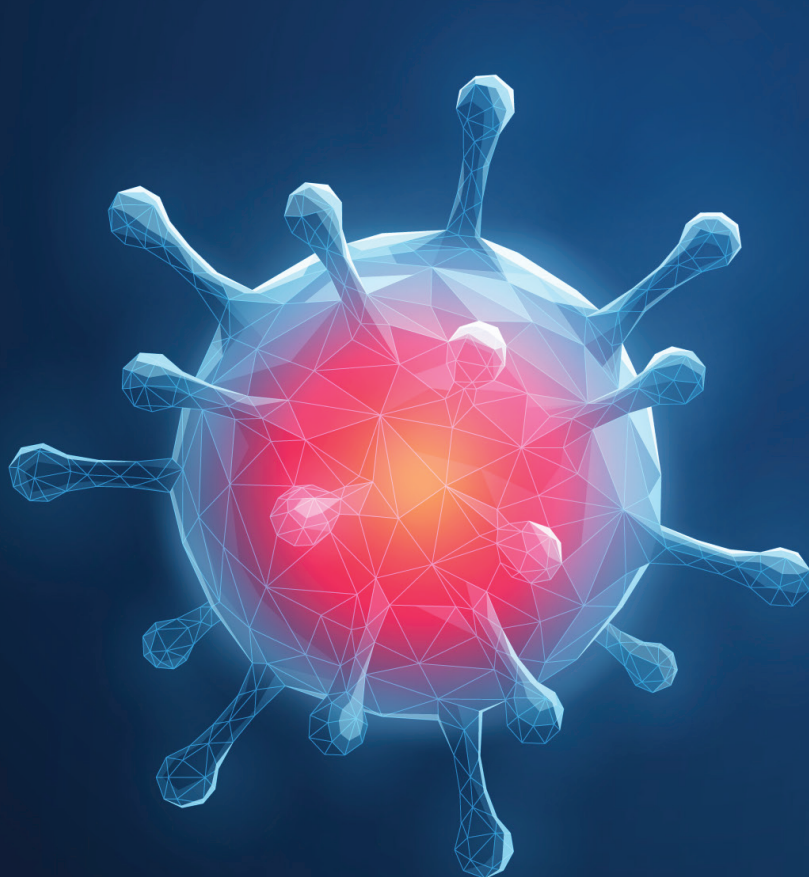
ecovasive
INFECTION CONTROL

FDA
EUA
AUTHORIZED



COVID-19 Rapid Antigen

The Ultimate POC Test With Reliable Results Within Minutes



Due to the highly contagious nature and global health crises, 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. Particularly, the identification of subclinical or asymptomatic cases is important to reduce or stop the infection because these individuals may transmit the virus. As an intended point-of-care (POC) designated test with a 10 min processing time, CareStart™ COVID-19 Antigen Test allows effective screening of COVID-19 infection on a large scale.

Features

- ✓ Lateral flow assay
- ✓ No equipment required
- ✓ Rapid results within **10 minutes**
- ✓ Minimally invasive specimen collection (nasopharyngeal swabs)
- ✓ Intended at POC setting (i.e., in patient care settings) by medical professionals

Clinical Features

- ✓ Detect SARS-CoV-2 nucleocapsid protein antigen with ultra high performance
- ✓ Identify acute infection with **88.4% sensitivity** and **100% specificity**

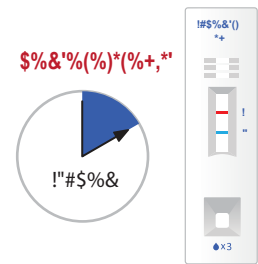
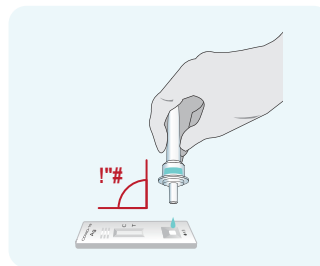
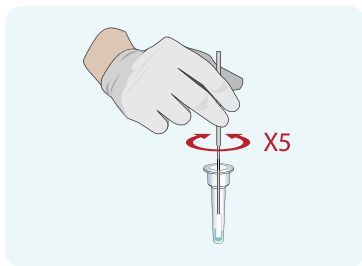


Test Principles

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 individuals who are suspected of COVID-19 by their healthcare providers.

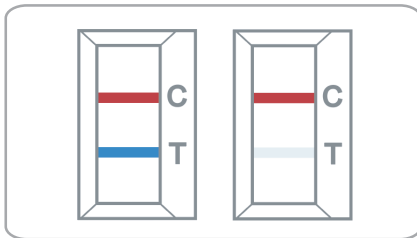
Procedure

- 1 Peel off aluminum foil seal and rotate the swab inside the extraction vial vigorously at least 5 times
- 2 Remove the swab, close the vial by pushing the cap onto the vial and squeeze the vial gently to release 3 drops of sample to the sample well
- 3 Read the test results between 10 and 15 minutes

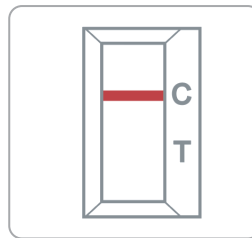


Results Interpretation

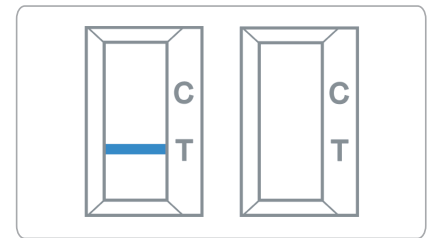
Positive



Negative



Invalid



NOTES

- 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 in the test region should be considered as positive.

NOTES

- Rerun the test one time using the remaining specimen in the extraction vial.

Order Information

Cat. No.	RCHM-02072
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

