

# CareStart™ COVID-19 ANTIGEN

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

- For use under an Emergency Use Authorization (EUA) only
- For professional use only
- For *in vitro* diagnostic use only



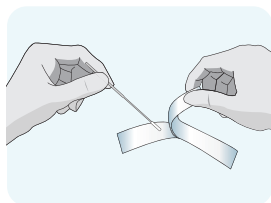
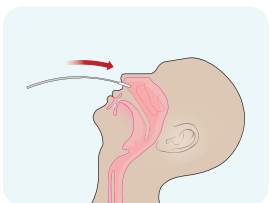
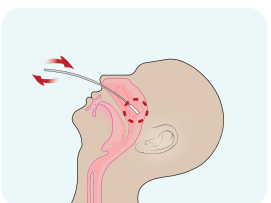
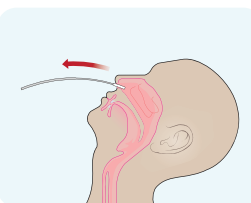

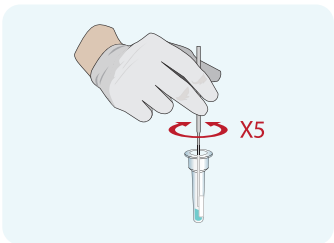
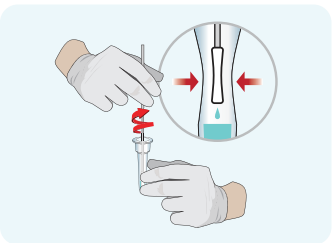
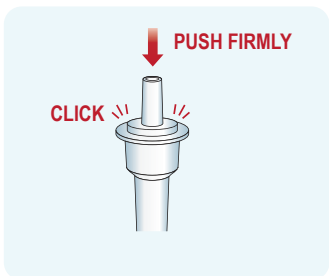
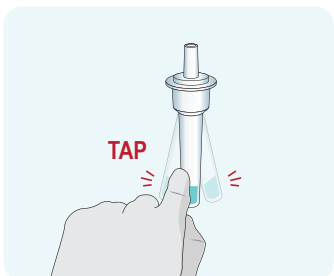
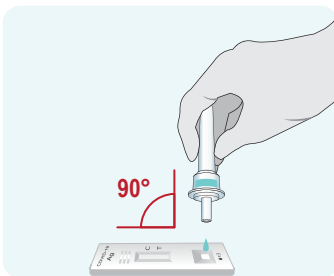
The CareStart™ COVID-19 Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in nasopharyngeal specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider.

## Features

- ✓ Fast and easy to use in Point-of-Care setting
- ✓ Qualitatively detect the SARS-CoV-2 nucleocapsid protein
- ✓ Use for nasopharyngeal swab specimen
- ✓ Fast results only in 10 minutes
- ✓ No special equipment or training required
- ✓ Identify individual's current infection status to COVID-19


# Test Procedure

## Specimen Collection Using Nasopharyngeal Swab


-  Remove a swab from the pouch.
-  Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.
-  Slowly rotate 5 times the swab over the surface of the posterior nasopharynx.
-  Remove the swab from the nostril.
-  Peel off aluminum foil seal.
-  Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.
-  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.
-  Close the vial by pushing the cap firmly onto the vial.
-  Mix thoroughly by flicking the bottom of the vial.
-  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.

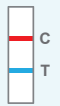
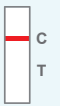
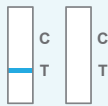
## Result Interpretation

**Start the timer.**



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



SARS-CoV-2 Positive	Negative	Invalid
		

**NOTES**

- The color intensity of the test line varies depending on the amount of SARS-CoV-2 antigen present in the specimen.
- Any faint colored-line in the test region should be considered as positive.

**NOTES**

- Re-run the test once more using the remaining specimen in the extraction vial.

## Order Information

Catalog No.	RCHM-02071		
Package Unit	20 tests/kit		
Kit Components	20 Test Devices	20 Extraction Vials and Caps	1 Package Insert
	1 Positive Control Swab	1 Negative Control Swab	1 QRI
	20 Nasopharyngeal Swabs		