

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 prescription only
- For *in vitro* diagnostic use only



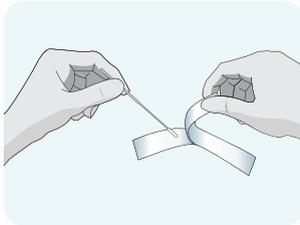
The CareStart™ COVID-19 Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in nasal or nasopharyngeal specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider.

Features

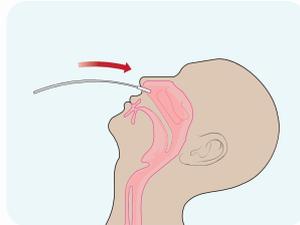
- ✓ Fast and easy to use in Point-of-Care setting
- ✓ Qualitatively detect the SARS-CoV-2 nucleocapsid protein
- ✓ Use for nasal and nasopharyngeal swab specimen
- ✓ Fast results only in 10 minutes
- ✓ No special equipment or training required
- ✓ Identify individual's current infection status to COVID-19

Specimen Collection and Handling

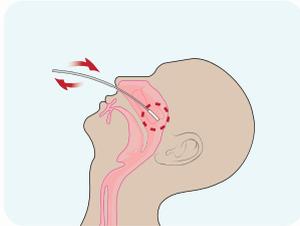
Nasopharyngeal (NP) Swab Collection



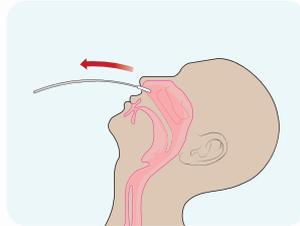
1 Remove a nasopharyngeal swab from the pouch.



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.

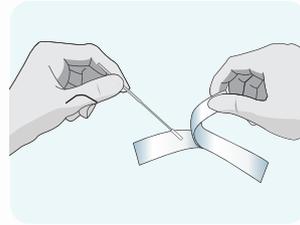


3 Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

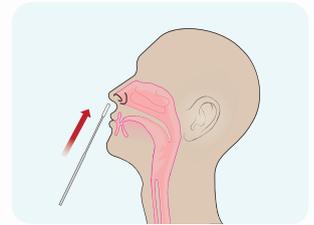


4 Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

Anterior Nasal Swab Collection



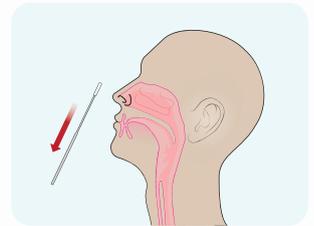
1 Remove a nasal swab from the pouch.



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.

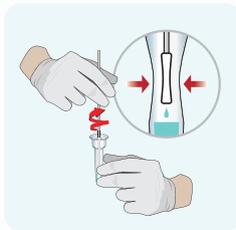
Test Procedures



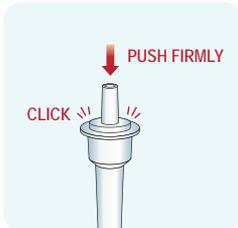
1 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



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



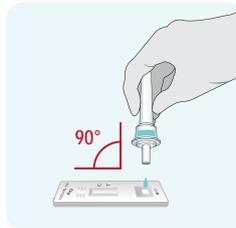
3 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



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



5 Mix thoroughly by flicking the bottom of the tube.

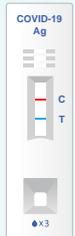


6 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.

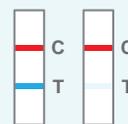
Start the timer.



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



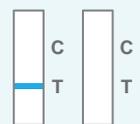
SARS-CoV-2 Positive



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 Nasal or nasopharyngeal swab		