

CareStart™ COVID-19 Antigen Home Test

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

- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Storage and Stability

- Store the test kit as packaged between 1 ~ 30°C.
- The test device must remain in the sealed pouch until use.
- Do not freeze any contents of the kit.
- For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit <http://www.fda.gov/covid-tests>.

Disposal

Dispose of all used test kit components and patient samples in household trash.

Specimen Collection and Handling

Acceptable specimen type for testing with the *CareStart™* COVID-19 Antigen is a direct anterior nasal (nares) swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results. Process the test swab sample immediately after collection (specimens are stable up to 4 hours in extraction buffer). Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

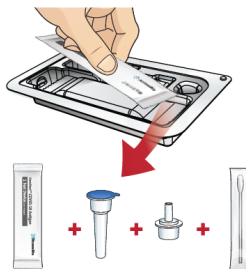
Instructions for Running the Test

IMPORTANT: Do not open kit components until instructions to do so. Follow the in-app self-paced, step-by-step instructions or paper instructions printed on the QRI as below.

- 1** Wash your hands thoroughly for at least 20 seconds before the test.



- 2** Unpack the test components from the tray.



- 3** Remove the test cassette and place it on a flat, clean surface.



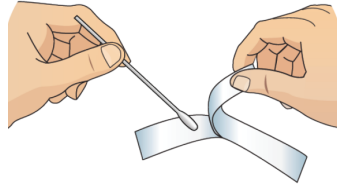
CareStart™ COVID-19 Antigen Home Test

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

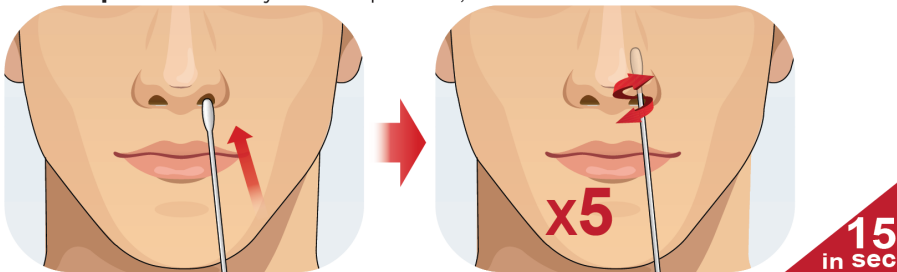
- 4** Locate the extraction vial and gently peel off the aluminum foil seal, being sure to keep the vial upright and place it in the packaging tray.



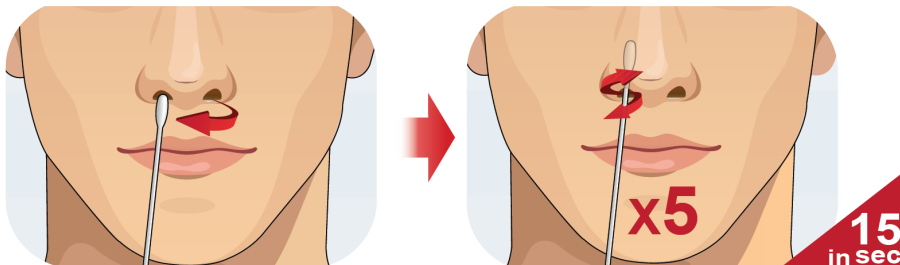
- 5** Locate a nasal swab and remove from the pouch. Be careful not to touch the swab tip.



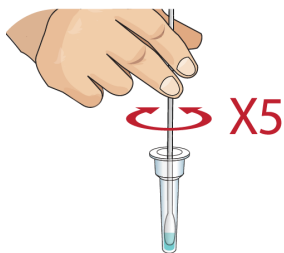
- 6** Gently insert the swab no more than 3/4 inch into the **LEFT** nostril. Then, slowly rotate the swab at least **5 times** in a circular path pressing gently against the inside walls of your nostrils for a total of **15 seconds**. **Do not just spin the swab.** If you have questions, see the CDC Guidelines.



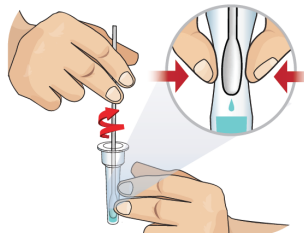
- 7** Gently remove the swab from the **LEFT** nostril and place directly into the **RIGHT** nostril, repeating the process of rotating at least **5 times** in a circular path pressing gently against the inside walls of your nostrils for a total of **15 seconds**. **Do not just spin the swab.** Remove the swab from the RIGHT nostril.



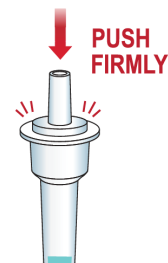
- 8** Place the swab into the extraction vial and rotate the swab at least 5 times **against the walls of the vial**.



- 9** Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.



- 10** Close the vial by pushing the cap firmly onto the vial.



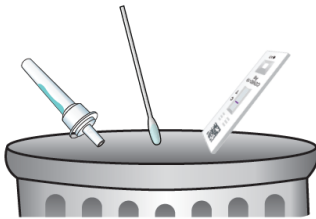
CareStart™ COVID-19 Antigen Home Test

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

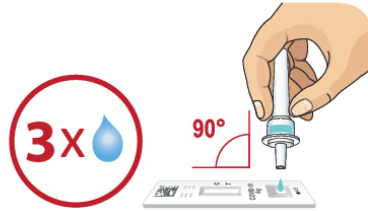
- 11** With your finger, mix thoroughly by flicking the bottom of the vial.

**Disposal**

Dispose of all used test kit components and swab samples in household trash.



- 12** 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.



- 13 Start a timer.**
Read the result at **10 minutes**. The test result should not be read after 15 minutes.



IMPORTANT
Do not move or lift the test cassette during this time. Do not exit the mobile app during this process.