REF RCHM-02071

QRI-RCHM-E / Rev. C / Apr. 15, 2021

Quick Reference Instructions for *CareStart*™ COVID-19 Antigen | **Rapid Diagnostic Test for Detection of SARS-CoV-2 Antigen**

For Emergency Use Authorization (EUA) Only

The *CareStart*™ COVID-19 Antigen test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are either suspected of COVID-19 by their healthcare provider within first five days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

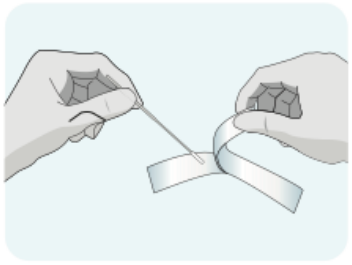
Rx Only IVD 1°C 30°C

IMPORTANT!

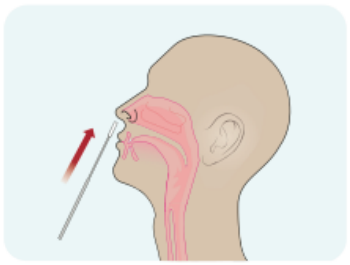
- Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
- Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information.
- Biotin Interference: False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (> 10 mg per day). Biotin levels of 2.5 µg/mL have been demonstrated to result in false negative test results.
- The extracted sample must be used within 4 hours of preparation when stored at room temperature.
- 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

SPECIMEN COLLECTION AND HANDLING

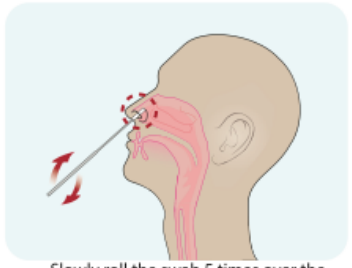
Anterior Nasal Swab Collection



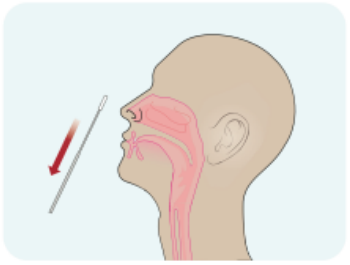
1 Remove a nasal swab from the pouch.



2 Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.



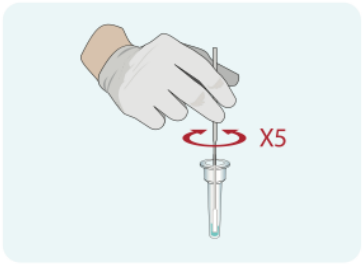
3 Slowly roll the swab 5 times over the surface of the nostril. Using the same swab, repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.



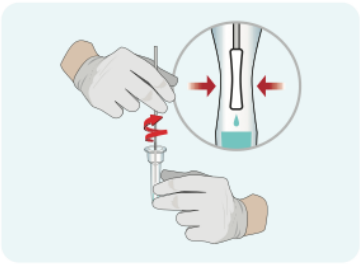
4 Slowly remove the swab from the nostril while rotating it.

TEST PROCEDURES

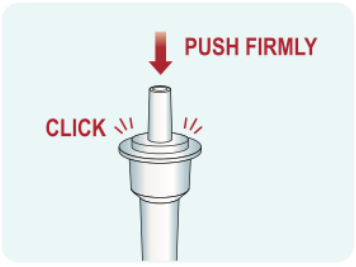
1 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



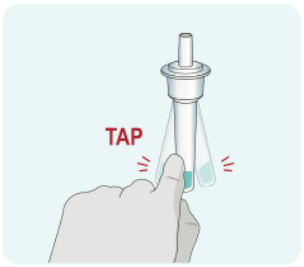
2 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



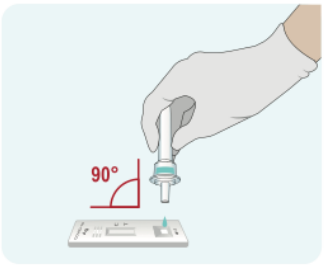
3 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



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

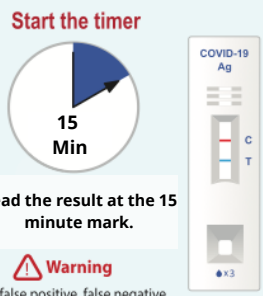


5 Mix thoroughly by flicking the bottom of the tube.



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.

NOTE: Refer to the Package Insert for the cautions.



Result Interpretation

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 results are presumptive. 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,particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

Invalid

If the red-colored line in the control region "C" is not visible, the result is invalid. Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.

External Control Swab Test: It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the nasopharyngeal swab test procedure provided in this package insert or the quick reference instruction card.

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If used on asymptomatic individuals for serial testing, a second test should be performed with at least 24 hours (and no more than 48 hours) between tests. For serial testing, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as, an individual with a close contact or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.