



Quick Reference Guide for COVID-19 Ag Rapid Test



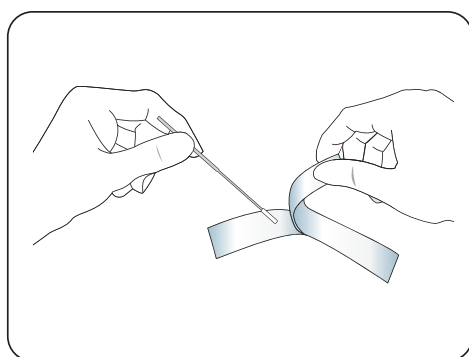
FOR CLINICAL USE ONLY

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

IMPORTANT

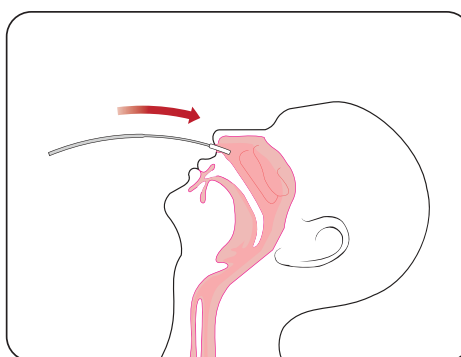
- Refer to the Instructions for Use for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
- Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines.
- The extracted sample must be used within 2 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 HANDLING AND COLLECTION



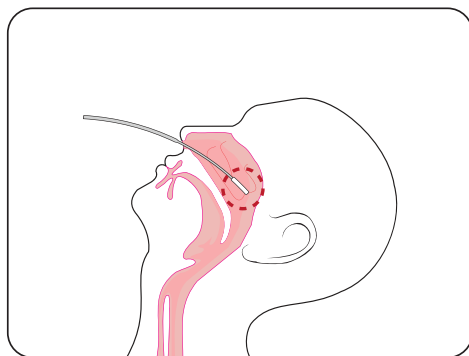
STEP ONE

Wearing nitrile or latex gloves, remove a nasopharyngeal swab from the sealed packaging.



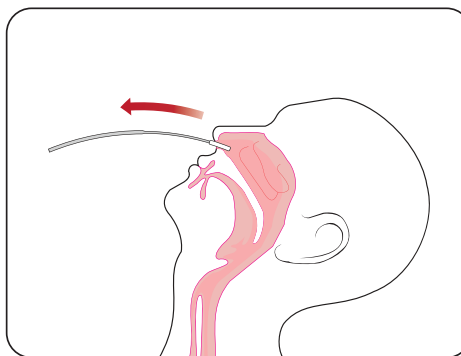
STEP TWO

Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.



STEP THREE

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



STEP FOUR

Slowly and carefully remove the swab from the nostril while continuing to gently rotate it.

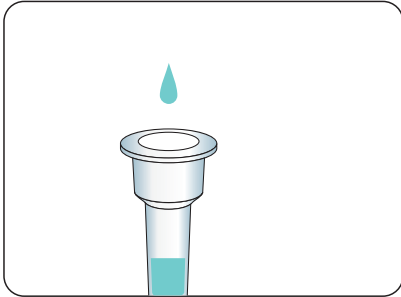




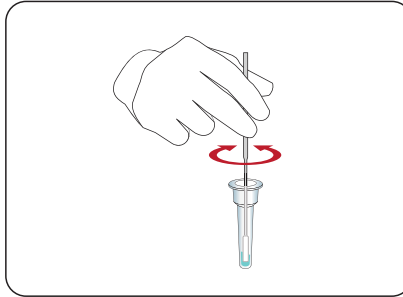
Quick Reference Guide for COVIX-19 Ag Rapid Test



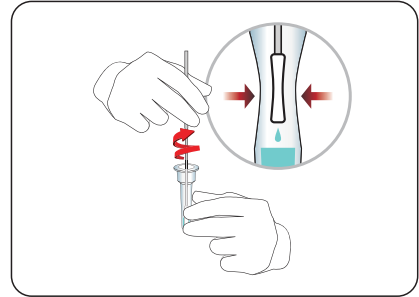
TEST PROCEDURE



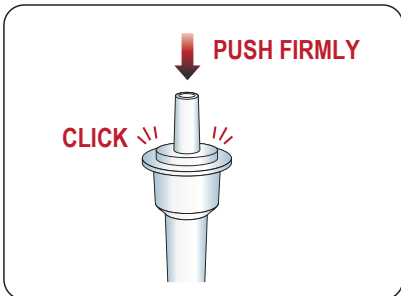
STEP ONE
Add 6 drops of Antigen Extraction R1 Buffer to an included Antigen Extraction Tube.



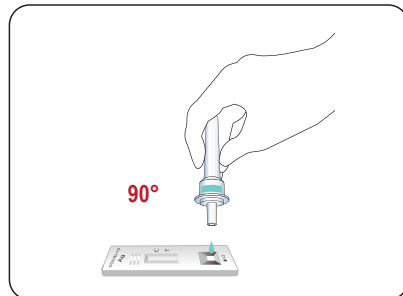
STEP TWO
Place the swab into the Antigen Extraction Tube and rotate the swab for approximately 10 seconds.



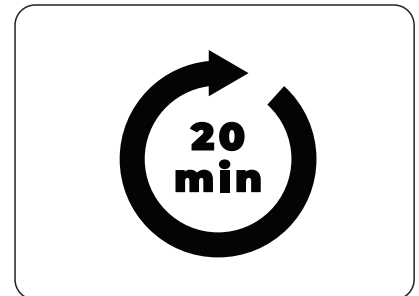
STEP THREE
Remove the swab while rotating against the Extraction Tube, and squeeze the sides of the vial to release any liquid from the swab.



STEP FOUR
Seal the Extraction Tube with the included nozzle cap.



STEP FIVE
Invert the Extraction Tube and hold the sample vertically above the Specimen hole on the test cassette (S). Place two drops of specimen into the hole.



STEP SIX
Wait 20 minutes before interpreting the results on the test cassette.

INTERPRETATION OF RESULTS

NEGATIVE RESULT	The C line is visible, and the T line is not visible. Negative results do not rule out a COVID-19 infection. Persons who test negative but continue to experience COVID-19 symptoms may still have SARS-CoV-2 infection and should consult with their healthcare provider.
POSITIVE RESULT	The C line and the T line are both visible, indicating a detection of COVID-19 antigens. Even if the T line is very faint or not uniform the test result should be interpreted as a positive. Follow up with a healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Positive results should be reported to local public health authorities where required.
INVALID RESULT	If the C line is not visible, regardless of the T line being visible or not, the test is invalid.

