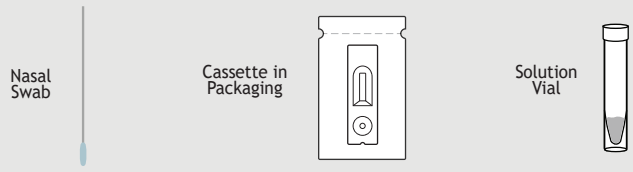
ASSURE-100

Rapid COVID-19 Test Kit | QUICK REFERENCE INSTRUCTIONS

- For Use Under an Emergency Use Authorization (EUA) Only.
- For in vitro diagnostic use.
- For prescription use only.
- For use with kit-provided anterior nasal swabs only.

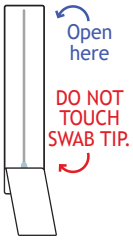
The Assure-100 Rapid COVID-19 Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first eight (8) days of symptoms onset.

KIT CONTENTS

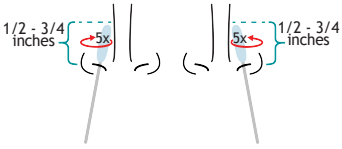


TEST PROCEDURE STEPS

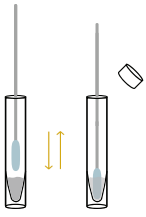
1 **REMOVE** nasal swab from packaging. Do not touch the swab tip.



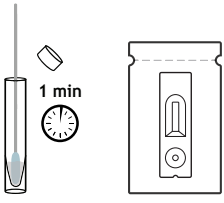
2 **INSERT** entire soft part of the swab into one nostril (½-¾ inches). Rub swab against the inside wall of nostril. Make at least 5 big circles, taking a total of 15 seconds. **Do not just spin the swab.** Repeat in the other nostril.



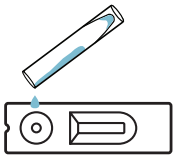
3 After swabbing each nostril, **PLACE** swab into the vial, tip first. **PLUNGE** swab in vial for 10 seconds by rapidly moving swab up and down.



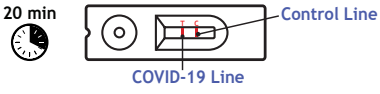
4 **PUSH** swab all the way to the bottom of the vial and leave for one minute. Following this, discard swab and open cassette package.



5 Place test cassette flat on a level surface and **POUR** all liquid content gently into the cassette well. It is normal for some of the liquid to remain in the bottom of the vial.



6 **WAIT** 20 minutes. Results interpretation continued on other side.



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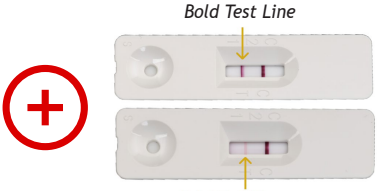
Refer to the Instructions for Use for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test. Positive test results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as SARS-CoV.

ASSURE support line: Further information can be obtained by contacting info@assure-test.com or by calling +1.855.929.6011

RESULT INTERPRETATION

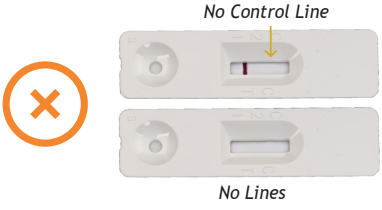
Read the results at 20 minutes.
Do not read the results before 20 minutes or after 30 minutes.
Interpretation before 20 minutes or after 30 minutes may yield false results.

Positive results may appear as bold or as faint as shown in the examples below. The appearance of ANY shade of pink-to-red test line AND the appearance of a pink-to-red control line indicates a positive result for the presence of SARS-CoV-2 antigen. A positive result does not rule out co-infections with other pathogens.



Negative results will show ONLY a control line. A negative result means that SARS-CoV-2 antigen was not detected. A negative does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

Invalid results when no control line is present. Invalid tests should be repeated using a new specimen and new test cartridge.



PROCEDURE FOR CONTROL SWABS

1. Remove control swabs from labeled packaging.
2. Follow steps 3-6 of the Test Procedure steps.

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate complexity, high complexity, or waived tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.