Clarity COVID-19 Antigen Test Quick Reference Instructions

IMPORTANT:

- These are not the full Instructions for Use. Carefully read all instructions in the full Instructions for Use before starting the test. Failure to follow the instructions may lead to inaccurate test results. The manufacturer's instructions must be followed; failure to follow the test's instructions or modify the testing procedure will result in the test no longer meeting the requirements for waived classification.
- **This test comes in two test formats; ensure that you follow the correct reagent preparation step.**
- Do not use after the expiration date printed on the outside of the box.
- This test is only for use in patients with symptoms.
- Negative results are presumptive and must be confirmed as described in the Intended Use of the Clarity COVID-19 Antigen Test.
- Store the test kit at 36ºF - 86ºF (2ºC - 30ºC) in the original sealed pouch. Do not freeze. Bring the test to room temperature at least 30 minutes before use.
- Process freshly collected anterior nasal swab samples immediately, but no later than one hour after collection. If needed, the swab may be stored at room temperature 59ºF - 86ºF (15°C - 30°C) for 1 hour in a sterile container.
- Refer to Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from persons for COVID-19 at https://www.cdc.gov/ coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Reagent Preparation for Test Format A or Format B

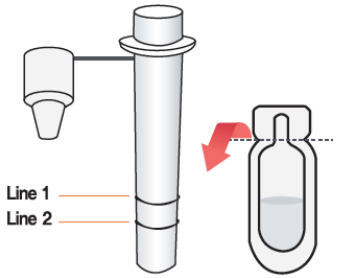
Test Format A -Step 1A

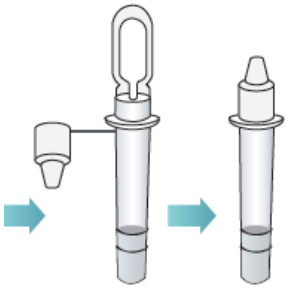
Remove the cap from the Reagent tube.

Proceed to Sample Collection

Test Format B- Step 1B

Or

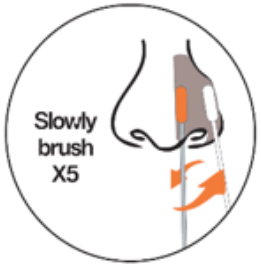




- Open the empty Reagent tube.
- Twist open the top of the ampule.
- Squeeze the ampule completely into the empty tube.
- Confirm the liquid is at or above line 1 of the reagent tube.

Proceed to Sample Collection

Sample Collection



- To collect the anterior nasal swab sample, tilt the patient's head back 70 degrees and insert the soft end of the swab into the patient's nostril no more than ¾ of an inch.
- Slowly rotate the swab 5 times for a total of 15 seconds, gently pressing against the inside of the patient's nostril.
- Remove the swab and repeat the same steps on the other nostril with the same swab.

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Sample Testing Procedure

Step 2

Insert the collected swab into the Reagent tube.

Step 3

Swirl the swab and move it up and down in the extraction buffer while squeezing the sides of the tube for 15 seconds.

Step 4

Remove the swab while squeezing the sides of the tube against the swab head to extract the most liquid.
Properly discard the swab.

Step 5

Firmly close the dropper tip onto the Reagent tube with the sample.

Step 6

Turn the Reagent Tube upside down. Gently squeeze 2 drops of the sample into the sample well of the test device.

Note: Incorrect number of drops can result in invalid or incorrect results.

Step 7

Read the results at 15 minutes. Do not read result more than 30 minutes after the sample application.

Note: Incorrect results can occur if read before 15 or after 30 minutes.

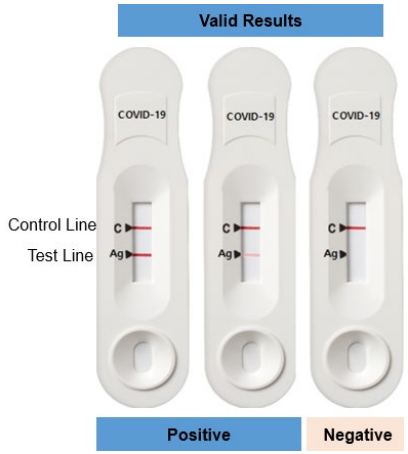
Results Interpretation

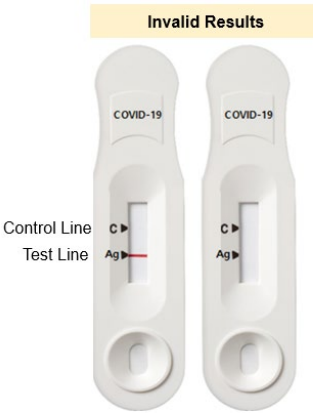
Positive: If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink test (T) line with a visible control (C) line should be read as positive. Repeat testing is not needed for individuals with a positive result.

Negative: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that the virus that causes COVID-19 was not detected in the sample.

Note: Negative results are presumptive. Patients who have an initial negative result with the Clarity COVID-19 Antigen Test should be tested again after 48 hours, or the test result should be confirmed with a molecular test.

Invalid: If a control (C) line is not visible, the test is not valid. Re-test with a new swab and a new test cassette. If the problem continues, please call +1-877-722-6339.





External Quality Control Test Step Instructions

Each kit has external positive and negative control swabs. These controls can be used to determine that the test performs as expected. Process the controls as described in the Test Procedure section. It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user.

Intended Use

The Clarity COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the rapid, qualitative detection of SARS-CoV-2 nucleoprotein protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 4 days of symptom onset.

The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Clarity COVID-19 Antigen Test and followed up with a molecular test.

Refer to the package insert/instructions for use for the full intended use statement.

Assistance:

For questions or technical support, please contact the Clarity Diagnostic Technical Support team at +1- 877-722-6339 or chat with us on our website www.ClarityDiagnostics.com

Manufactured for: **Clarity Diagnostics, LLC**
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Glossary

Rx ONLY Prescription use only	IVD For In Vitro use only	Σ 20 Contains sufficient for 20 determinations	
LOT Batch code	Use by	Temperature limitation	Consult instructions for use
REF Catalog number	CONTROL + Positive control	CONTROL − Negative control	Do not re-use

Cat No: CLA-COV19-AG20
Part No: EP-3452CD-QRI-R0
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