CLARITY

Clarity COVID-19 Antigen Test

QUICK REFERENCE INSTRUCTIONS

For *In Vitro* Diagnostic Use.
For Prescription Use Only.
For use in a CLIA Complexity: Waived Environment.
This CLIA-waived kit configured for testing anterior nasal swab samples.

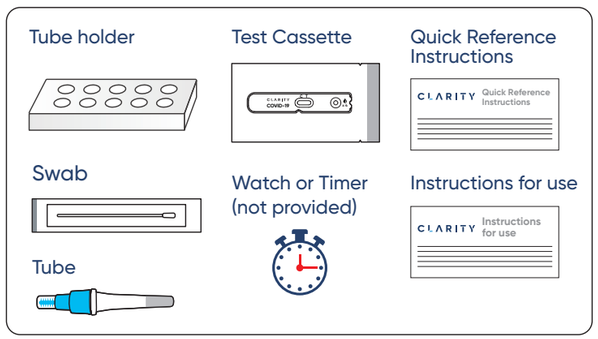
CLIA COMPLEXITY: WAIVED
A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA.
Failure to follow the instructions or modification to the test system instructions will result in the test being classified as high complexity.

Please read Quick Reference Instructions (QRI) and Instructions for Use (IFU) carefully before starting the test procedure.

STEP BY STEP INSTRUCTIONS

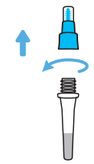
MATERIAL PREPARATION

1 Ensure you have all required testing components. Place the kit components on a flat surface.
NOTE: Ensure all test components are at room temperature (15°C-30°C / 59°F-86°F) before use.

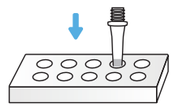


2 Check the expiration date of the test kit before use.
WARNING: The test must not be used beyond the expiration date listed on the packaging. Use of expired tests can lead to incorrect results.

3 Remove the large blue cap from the **TUBE**.

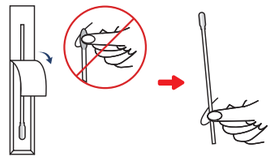


4 Place **TUBE** in the Tube Holder.

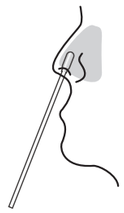


SAMPLE COLLECTION

5 Remove the **SWAB** from its wrapper.
Do not touch the tip of the swab.

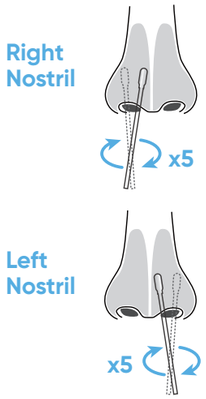


6 Gently insert the entire absorbent tip of the swab (3/4 of an inch) into the nostril.
WARNING: Do not insert the swab any further if you feel any resistance.



7 Firmly and slowly brush against the nasal wall in a circular motion **at least 5 times**. Remove the swab and repeat in the other nostril using the same swab. Take **at least 15 seconds** to collect the specimen and be sure to collect any nasal drainage on the swab.

WARNING: Be sure to rub BOTH nostrils with the same SWAB

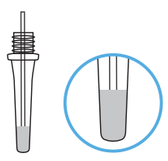


NOTE: With children, you may not need to insert the swab as far into the nostril and you may need another person to steady the child's head while swabbing.

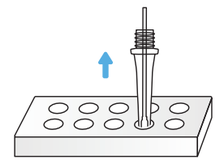
NOTE: Failure to swab properly may cause false negative results.

TEST PROCEDURE

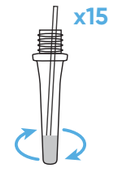
8 Immediately place the **SWAB** into the liquid inside the **TUBE**, and ensure it is touching the bottom of the **TUBE**.



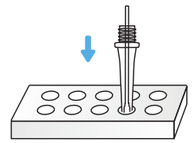
9 Remove the **TUBE** from the tube holder.



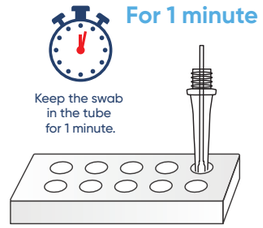
10 Stir the swab vigorously **at least 15 times**.



11 Place the tube back into the tube holder. Keep the swab inside of the tube for 1 minute.

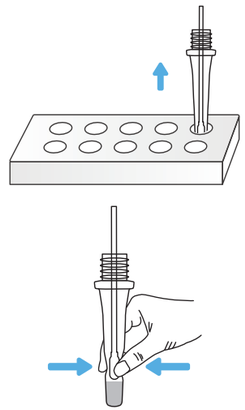


12 Start timer for 1 minute.

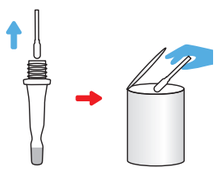


13 After 1 minute, take the tube out of the tube holder. **Remove the swab while squeezing the sides of the tube** to express as much liquid as possible from the swab.

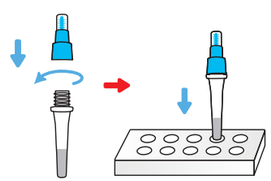
WARNING: Be sure to squeeze the tube while removing the swab.



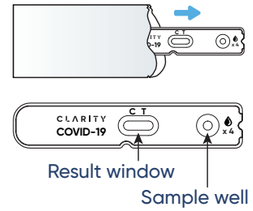
14 Dispose the **SWAB** in the trash.



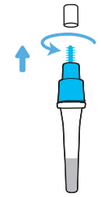
15 Screw the large blue cap back onto the **TUBE**. Place **TUBE** in the Tube Holder.



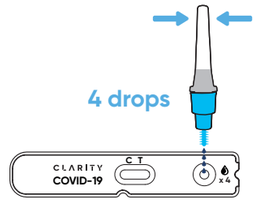
16 Remove the **TEST CASSETTE** from the sealed pouch and lay it flat.



17 Twist to open the small white cap at the top of the **TUBE**.



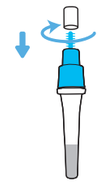
18 Add **4 drops** of sample into the sample well of the **TEST CASSETTE**.



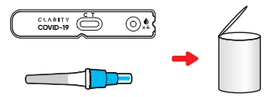
19 Wait **10 minutes**. And then read the result at 10 minutes as described in the next section **Interpretation of Results**.

DISPOSE THE TEST KIT

20 Screw back the small white cap.



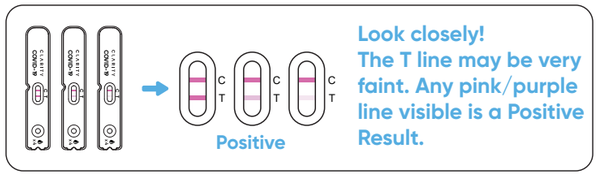
21 After the test is completed, dispose of the kit and its components in the trash.



INTERPRETATION OF RESULTS

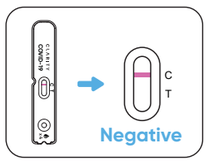
WARNING: Do not read the result before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may result in false or invalid results.
Look carefully for a C line for a valid test result. For positive result, look carefully for a T line.

Positive Result



If the Control (C) line and the Test (T) line are visible, the test result is Positive. Any faint visible pink or purple test (T) line with the control (C) line should be read as positive.
Do not need to repeat testing if you have a positive result at any time.

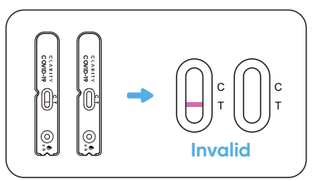
Negative Result



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 and may be confirmed with a molecular assay, if necessary, for patient management. Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours or followed up with a molecular test.

Invalid Result



If a Control (C) line is NOT visible, DO NOT CONTINUE reading the results. It means that your test result is INVALID.

NOTE: An invalid test result means that the test is unable to determine if individuals are infected with SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new kit and sample. If the problem persists, please call at 1-877-722-6339.

INTENDED USE

The Clarity COVID-19 Antigen Test is a visually read lateral flow immunoassay test intended for the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection. 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 with a molecular test.

A negative test result is presumptive, and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.
Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.
Performance characteristics for SARS-CoV-2 were established from April 2023 to February 2024 when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

WARNINGS AND PRECAUTIONS

- **Do not use this test when individuals have symptoms for more than 5 days or if Individuals have no symptoms.**
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- Check the test's expiration date. Do not use kit past its expiration date. Use of expired tests can lead to incorrect results.
- The test device should remain in its original sealed pouch until ready for use to keep all test components dry.
- Do not use if any of the test kit components or packaging is damaged.
- Once opened, the test device must be used immediately.
- Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.
- Do not mix components from different kits or different lots.
- Wear protective clothing such as safety mask or other face covering, laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- Do not reuse the test cassette, processing solution, or swab.
- Not for use with viral transport media (VTM).
- When collecting a sample, only use the swab provided in the kit.
- Inadequate or inappropriate sample collection, test storage, or test transport may yield false test results.
- Testing should be performed in an area with good lighting.
- **Keep test kit and materials out of the reach of children and pets before and after use. Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the reagent solution contacts the skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222.**

Chemical name	Harms (GHS Code) for each ingredient	Concentration
ProClin 300	Causes serious eye irritation (H319) Causes mild skin irritation (H316)	0.02%
Tris-HCl	Causes eye irritation (H320) Causes skin irritation (H315)	1.2%
Tween 20	Causes eye irritation (H319) Causes skin irritation (H315)	0.5%

LIMITATION

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between April, 2023 and February, 2024. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
  All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision - such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test has not been validated for use by those with color-impaired vision.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample.
- This test does not distinguish between SARS-CoV and SARS-CoV-2.
- The test results should be interpreted in conjunction with other clinical and laboratory data available to the healthcare provider.
- A false negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.

EXTERNAL QUALITY CONTEOL

To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab. It is recommended that the positive and negative controls be run once for each untrained operator, once for each new shipment of kits –provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.
If external controls do not perform as expected, testing of individuals should not be performed. Repeat the test or contact Clarity Diagnostics Group, LLC at 1-877-722-6339 a or chat with us on our website www.ClarityDiagnostics.com

STORAGE AND STABILITY

- The test kit should be stored in a dry place between 36°F-86°F (2°C-30°C). The test kit is stable until the expiration date on kit box and pouch. Do not use beyond the expiration date.
- Ensure all kit components are at room temperature 59°F-86°F (15°C-30°C) before use.
- Keep away from direct sunlight, moisture and heat.
- Do not freeze any of the test kit components.

ASSISTANCE

If the test does not perform as expected, please call 1-877-722-6339 (8:00 a.m. to 6:00 p.m. EST M-F).

INDEX OF SYMBOLS

Keep away from sunlight	Store between 36°F-86°F (2°C-30°C)	Keep dry
Do not re-use	REF Catalogue number	LOT Batch code
Use-by date (Expiration date)	Contains sufficient for <n> tests	IVD *In Vitro* diagnostic medical device
Consult instructions for use	Do not use if package is damaged	Rx ONLY Prescription Use Only

Manufactured For:
Clarity Diagnostics Group, LLC
1701 Green Rd, Suite A
Deerfield Beach, FL 33064
1-877-722-6339
www.claritydiagnostics.com

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