

**RAPID RESULTS:
10 MINUTES OR LESS!**

Sienna™ COVID-19 Antigen Rapid Test

Nasopharyngeal Swab



*For prescription use only
For professional in-vitro diagnostic use only*

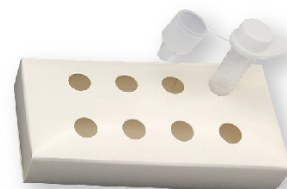
The COVID-19 Antigen Rapid Test Cassette (*Nasopharyngeal Swab*) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasopharyngeal swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

DEPENDABLE ACCURATE RESULTS

- Sensitivity 93.8%
- Specificity 99.2%*
- Accuracy 98.7%

UNMATCHED CONVENIENCE

- **Individual Buffer Vials**
(Helping multiple operators at same time)
- **Visual Results Easy to Interpret**
- **10 Minute Test Time**

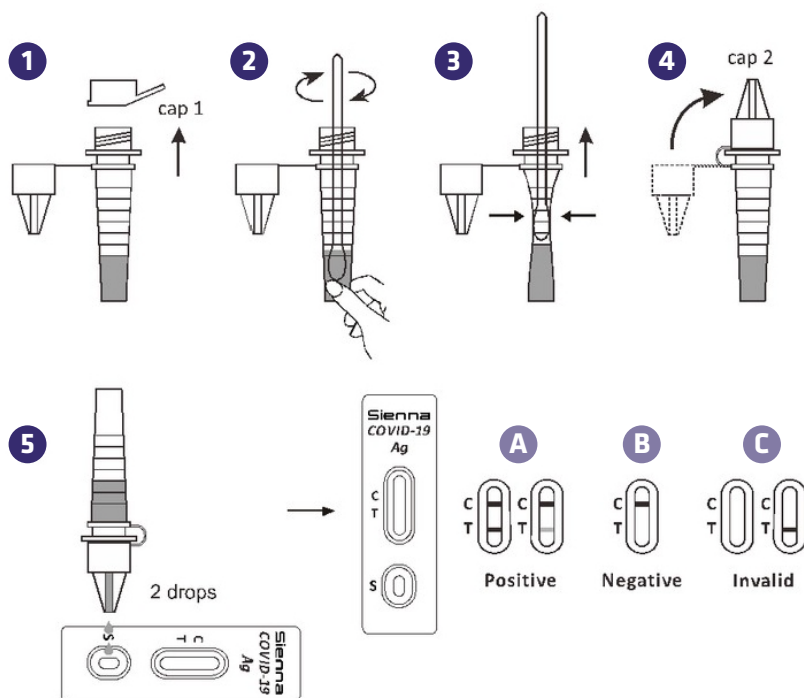


EACH BOX CONTAINS (25) Individually Pouched Test Cassettes,
(25) Extraction Buffer Tubes, (25) Sterile Swabs and (1) Instruction Sheet Insert.

DIRECTIONS FOR USE

Allow the test cassette, specimen, supporting buffer to equilibrate to room temperature 15°C – 30°C (59°F – 86°F) prior to testing.

- 1 Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
- 2 Place the extraction buffer in the workstation. Open the cap 1 (See illustration 1) and place the swab specimen in the extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. (See illustration 2).
- 3 Remove the swab while squeezing the swab head against the inside of the extraction buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol (See illustration 3).
- 4 Tighten cap 2 (See illustration 4), place the test cassette on a clean and level surface.
- 5 Add 2 drops of the solution to the sample well (See illustration 5) and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF THE RESULTS

- A Positive***
Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that COVID-19 was detected in the specimen.
- B Negative**
One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that COVID-19 antigen is not present in the specimen, or is present below the detectable level of the test.
- C Invalid**
Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact the manufacturer or your supplier.

**NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of COVID-19 Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.*

Order Information

CATALOG NO.	PRODUCT	CONTENTS	CW/EAU STATUS
102241	Sienna™ COVID-19 Antigen Rapid Test Cassette	<ul style="list-style-type: none"> • 25 Test Cassettes • 25 Buffer Tubes • 25 Sterile Swabs • 1 Product Insert 	CE

For details on how this test should be distributed and used in the U.S., please visit:
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>