Sienna COVID-19 Antigen

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

(Nasopharyngeal)

For use under an Emergency Use Authorization (EUA) only

For prescription only

For *in vitro* use only

The **Sienna™ COVID-19 Antigen Rapid Test Cassette** is a rapid chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swab (NP) specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset.

This test 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 not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories.

Unmatched Convenience

- Easy to use and authorized by the FDA under an EUA for use in Point of Care settings
- No additional equipment or training required
- Results in just 10 minutes
- Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2
- Used with nasopharyngeal swab specimen
- Individual buffer vials and sterile swabs allow multiple individuals to be tested simultaneously

www.genscopharma.com info@genscopharma.com 855.743.6726

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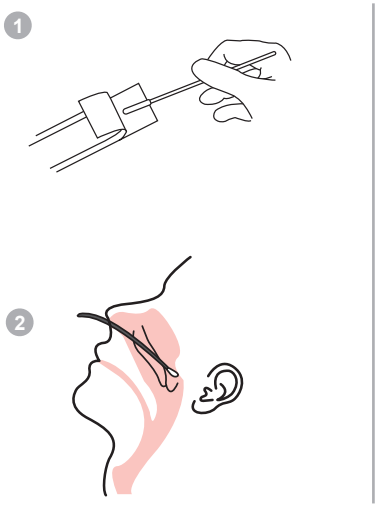
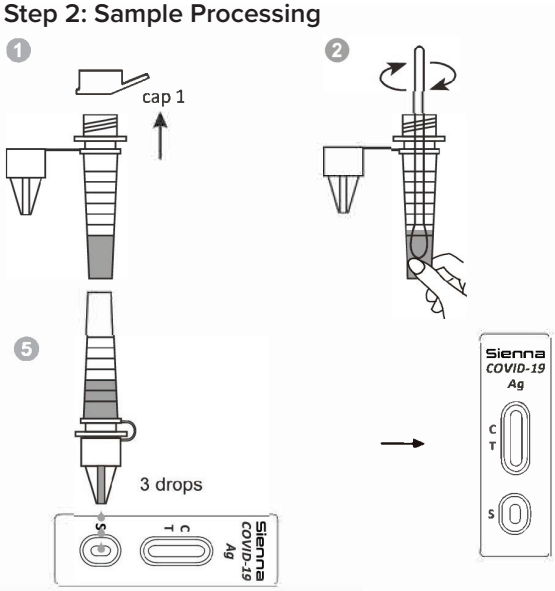
Test Procedure

Step 1: Sample Collection



Step 2: Sample Processing

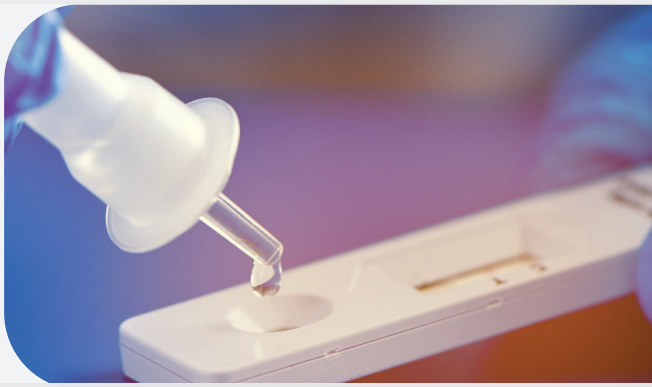


Kit Contents

- Extraction Buffers
- Sterile NP Swabs
- Quick User Guide
- Workstation
- Instructions for Use
- Individually Pouched Tests Cassettes
- Negative Control Swab
- Positive Control Swab

Quantity: 25 Tests per kit

For professional *in-vitro* diagnostic use only.



Medical SKU	Product Name	Quantity
COV-19C25S	Sienna COVID-19 Antigen Rapid Test	25 Tests

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.

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