

Sienna COVID-19 Antigen Rapid Test Kit

Results in 10-20 minutes using a Nasopharyngeal swab

Test Details

The Sienna COVID-19 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasopharyngeal swab. The identification is based on the monoclonal antibodies specific for the Nucleocapsid protein of SARS-CoV-2. It is intended for professional in-vitro diagnostic use, prescription use, and Emergency Use Authorization only.

Accurate Results

- Sensitivity: 87.5%
- Specificity: 98.9%

Unmatched Convenience

- Visual Results: Easy to interpret.
- Fast Results: 10–20 minute test time.
- Individual Buffer Vials and Sterile Swabs:

Helps in testing multiple individuals simultaneously.

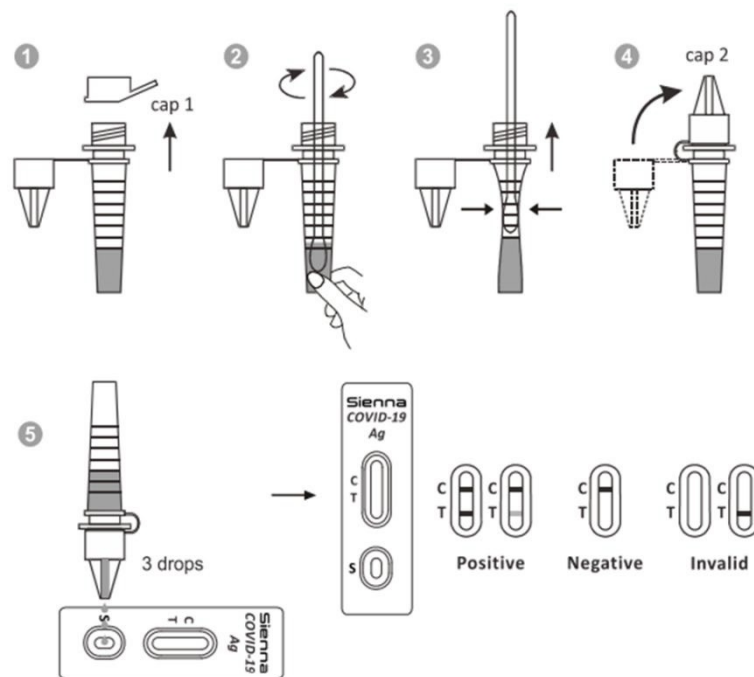


1. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
2. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
3. The emergency use of this product 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 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 authorization is revoked sooner.

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During the testing process, the extracted specimen reacts with the antibody of the SARS-CoV-2 nucleocapsid protein that are coated onto particles. The mixture migrates into the membrane to react with the antibody for the SARS-CoV-2 nucleocapsid protein on the membrane and will generate one colored line in the test regions. The presence of this colored line in the test regions indicates a positive result. A colored line will always appear in the control region to serve as a procedural control if the test has been performed correctly.

Test Procedure



Kit Contains:

- (1) IFU
- (25) Individually pouched Cassettes
- (1) Workstation
- (25) Buffer Tubes
- (25) Sterile Swabs
- Positive Control
- Negative Control