Seroclinix

Innovative Diagnostic Solutions for Today's Healthcare

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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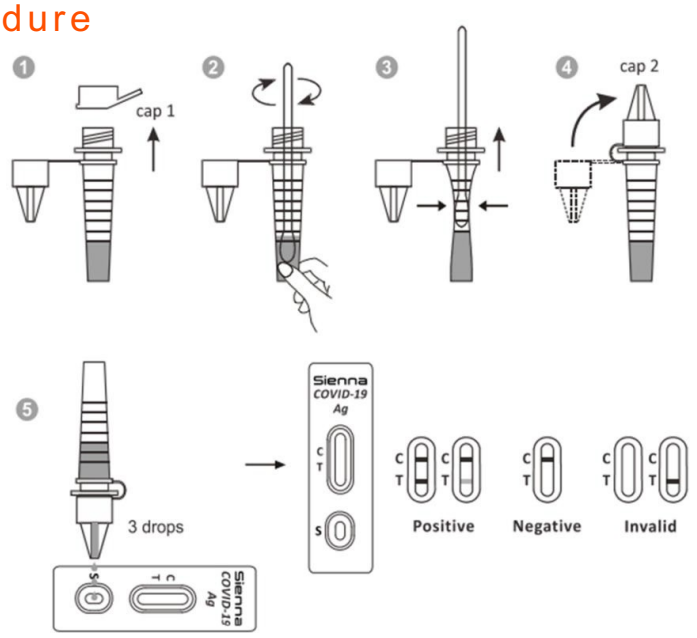
Test Procedure



Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as a reference method for the COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab). Specimens were considered positive if PCR indicated a positive result. 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 isanticipated 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.

Method		RT-PCR		Total Results
Sienna™ COVID-19 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	35	1	36
	Negative	5	92	97
Total Results		40	93	133

Relative Sensitivity:	35/40 87.5% (95% CI: 68.6%-93.0%)
Relative Specificity:	92/93 98.9% (95% CI: 94.2%-99.9%)

Limit of Detection

The Limit of Detection of the Sienna™ COVID-19 Antigen Rapid Test Cassette is 1.25×10^3 $TCID_{50}$/mL