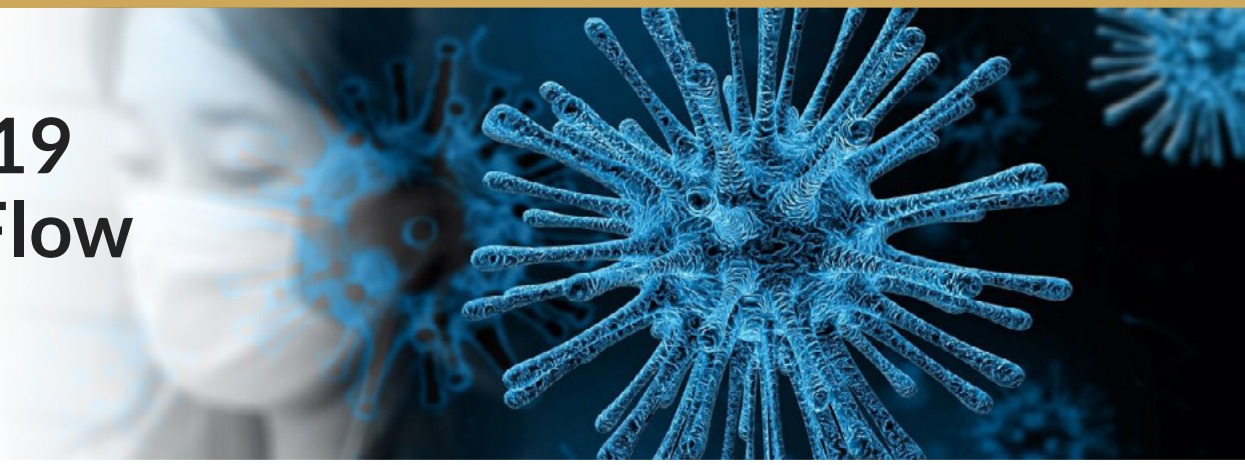
sona ·nanotech·

COVID-19 Lateral Flow Assay



SONA COVID-19 Antigen Test Device

COVID-19 Rapid Antigen Test

The Sona Nanotech COVID-19 Lateral Flow Assay is an immunochromatographic assay for the qualitative detection of the spike protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimens from individuals who are suspected of having COVID-19.

- Reliable, High Performance:
  - 96% Sensitivity (Laboratory Results)
  - 96% Specificity (Laboratory Results)
- Accessible and portable tool for Point-of-Care (POC) testing
- Freedom from equipment - no analyzer required for reading results
- Express results within 15 minutes

Clincial In-field Performance

Sensitivity:
84.6%*

Specificity:
90.0%*

Clinical Study Population:
Clinical performance characteristics of the Sona COVID19 antigen test was evaluated in a prospective study, at two different sites, where 99 patients were enrolled into the study and tested. Patients were a mix of symptomatic patients suspected of COVID19 (59) and asymptomatic (40) patients.

Specifications

Test Time:
15 Minutes

Storage:
Test kit can be stored at 2 -30°C (35-86°F). DO NOT FREEZE

Sample Type:
Nasopharyngeal swab

94% within first 8 days of onset of symptoms

EC REP
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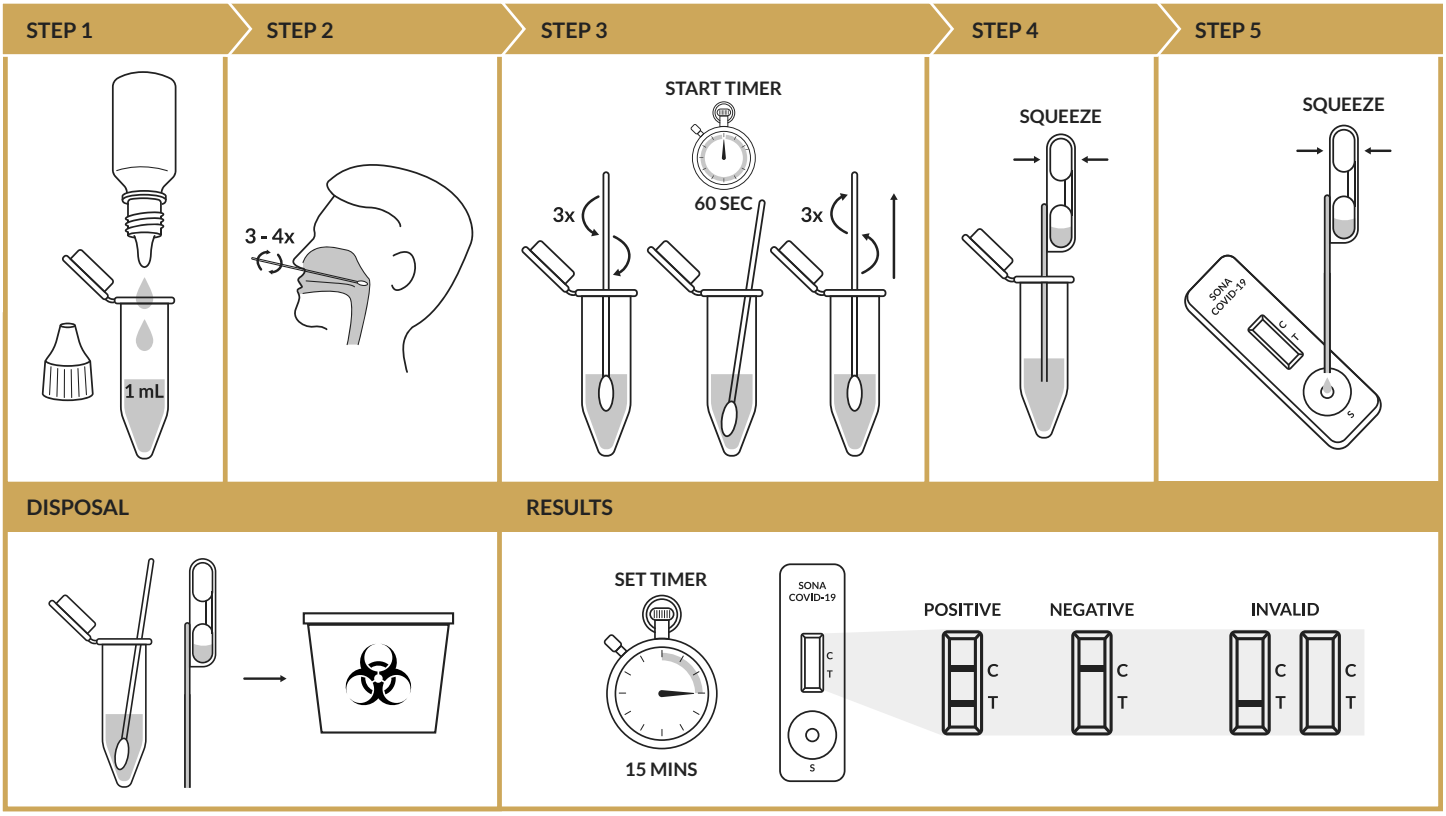
COVID-19 Lateral Flow Assay

Test Procedure



Intended Use: COVID-19 Lateral Flow Assay is an immunochromatographic assay for the qualitative detection of the spike protein antigen from SARS-CoV-2 in nasopharyngeal (NP)swab specimens from individuals who are suspected of COVID-19 by their healthcare provider. The assay is intended for professional and laboratory use.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. A positive result does not rule out co-infections with other pathogens. The agent detected may not be the definite cause of disease. The Sona Nanotech COVID-19 Lateral Flow Assay does not differentiate between SARS-CoV and SARS-CoV-2.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. The Sona Nanotech COVID-19 Lateral Flow Assay is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

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SONA COVID-19 Antigen Test Device

Order Information:

Sona Nanotech COVID-19 Lateral Flow Assay

Catalog Number: CV2-25

Contact Sona Sales Team

Contact sales for additional information.

sales@sonanano.com

https://sonanano.com

1 902-209-2232

Kit Contents:

- Sona Nanotech COVID-19 LFA x25
- COVID-19 LFA Test Cartridge x25
- 1.5ml Microfuge Tube x25
- Dual Bulb Fixed Volume Pastette® (100µL) x25
- COVID-19 Reagent Solution Dropper Bottle (White Cap) 2 x 15ml
- Instructions for use IFU-CV2 x1
- Procedure Card PC-CV2 x1
- 25 Nasopharyngeal Swabs