



TECHNICAL SPECIFICATION

Product Name

Sure Status® COVID-19 Antigen Card Test (Home Test)

Manufacturer: Premier Medical Corporation Private Limited

**Unit II: A1-302, GIDC, Sarigam-396155. Dist. Valsad,
Gujarat, INDIA.**

An ISO 13485 & EN ISO 13485 Certified Company

Product Details			
1	Product Name	:	Sure Status® COVID-19 Antigen Card Test (Home Test)
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	SS03-NS-H

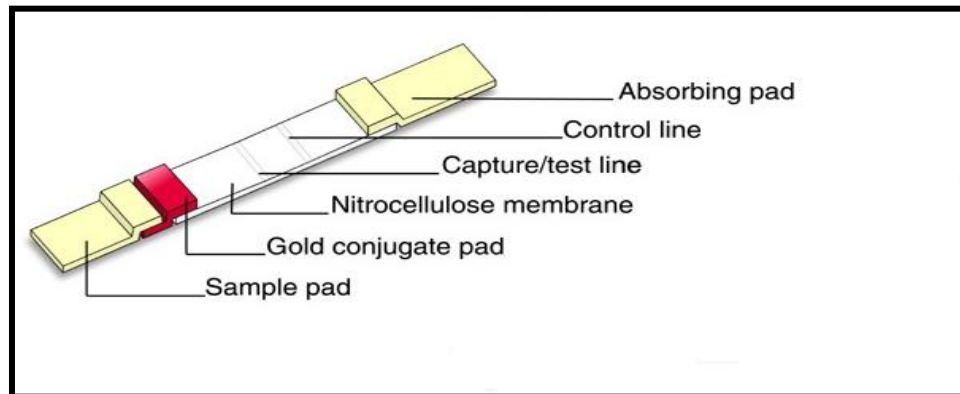
Intended Use:

Sure Status® COVID-19 Antigen Card Test (Home Test) is a single use, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 specific antigen in nasal swab from individuals aged 18 years or above who are suspected of COVID-19. Adult can collect nasal swab specimens from individuals aged 2-18 years who are suspected of COVID-19. This test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infections. A positive test result should be considered as a true positive & does not need reconfirmation by RT-PCR test. Negative results must be combined with clinical observations, patient history, and epidemiological information. Symptomatic individuals identified negative by Rapid Antigen Test (RAT) should be linked with RT-PCR test facility and subsequently get tested by RT-PCR to rule out COVID-19 infection. In the meantime, such individual will be urged to follow home isolation and treatment as a negative report on RAT may not be true negative in some cases.

Assay Principle:

The assay is based on sandwich immunochromatographic interaction between antigen and antibodies. The kit contains anti-coronavirus (anti Nucleocapsid) antibody molecules coated on nitrocellulose membrane as well as conjugated to colloidal gold as a detection agent. When the specimen is applied the test captures COVID-19 antigen (nucleocapsid antigen) between 2 antibody molecules, in case of positive specimen. This will lead to development of the Test line. While in case of negative specimens, there will not be any development of test lines. Control line will develop irrespective of positive/negative specimen status.

General Presentation of test strip of Sure Status® COVID-19 Antigen Card Test (Home Test)



Storage & Stability

Sure Status[®] COVID-19 Antigen Card Test (Home Test) should be stored at 4-30 °C. Do not freeze the kit or components. Pre-filled reaction buffer vial (unopened) & the unopened Test Device are stable until the expiry date printed on the label, when stored at room temperature 4-30 °C. The test device is sensitive to humidity and heat. Perform the test immediately after removing the Test Device from the foil pouch. The shelf life of the kit is as indicated on the outer package. Do not use test device and Pre-filled reaction buffer vial beyond the date of expiry.

Shelf Life:

Sure Status[®] COVID-19 Antigen Card Test (Home Test) has shelf life of 24 months.

Operational Characteristics:

Temperature range:

- Sure Status[®] COVID-19 Antigen Card Test (Home Test) is stable at temperature range of 4- 30°C.
- Operating Temperature range is room temperature (15-30°C)
- Test result interpretation time 15 to 20 minutes. Do not read the results after 20mins.

Certification:

1. Sure Status[®] COVID-19 Antigen Card Test (Home Test) is manufactured by Premier Medical Corporation Private Limited is ISO 13485 & EN ISO 13485 certified company.
2. ICMR Evaluated.

Kit components:

Each kit of Sure Status[®] COVID-19 Antigen Card Test (Home Test) contains:

- Individually pouched test device with desiccant.
- Nasal Swab.
- Pre-filled reaction buffer vial.
- Nozzle.
- Instructions for use in English language.
- Biohazard Bag