



TECHNICAL SPECIFICATION.

Product Name

Sure Status® COVID-19 Antigen Card 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
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	SS03

Intended Use:

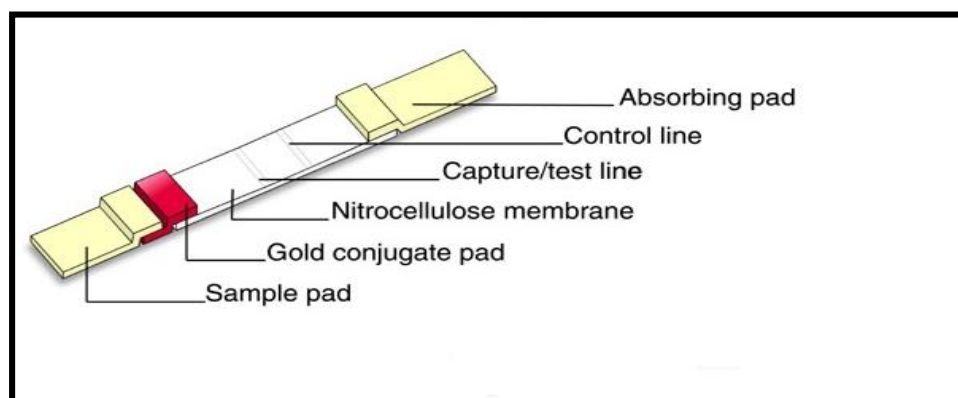
Sure Status[®] COVID-19 Antigen Card Test is a lateral flow immunochromatographic assay for qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider.

Sure Status[®] COVID-19 Antigen Card Test is for in vitro diagnostic use and intended as an aid to detection of nucleocapsid protein antigen in patient with clinical symptoms of SARS-CoV-2 infection. It provides only an initial screening test results and more specific alternative diagnosis method should be performed in order to obtain the confirmation of SARS-CoV-2 infections. The test is not automated and does not require any additional instrument. Test is designed to be performed by Laboratory professionals/trained users only.

Assay Principle

The detection kit uses the principle of immunochromatography: separation of components in a mixture through a medium using capillary force and the specific and rapid binding of an antibody to its antigen. Each cassette is a dry medium that has been coated separately with anti-coronavirus (anti Nucleocapsid) antibody molecule, this can be a monoclonal or a poly clonal antibody directed against nucleocapsid of 2019-nCoV and goat anti-chicken IgY antibody (control line). 2 free colloidal gold labeled antibodies, i.e anti-nucleocapsid antibody as well as chicken IgY, will be sprayed on the conjugate pad. Once specimen as a nasopharyngeal swab is collected and diluted in extraction buffer, this diluted specimen will be applied on sample pad. The specimen in buffer will pass through the conjugate pad and bind with anti-nucleocapsid protein antibody conjugated with colloidal gold on the conjugate pad. will form a complex of antigen-antibody colloidal gold and will migrate towards test and control lines. Application of diluted specimen will also rehydrate the colloidal gold conjugates sprayed in conjugate pads. Thus, the formed complex of antigen-antibody-colloidal gold will migrate through capillary action and binds with the coated antibody molecules at test line, thus providing reactive result. If there is no formation of antigen-antibody colloidal gold complex, it will not bind with the test line and there will not be any development of test lines. Chicken IgY conjugate with colloidal gold will bind with control line antibody irrespective of reactive/non-reactive specimens.

General Presentation of test strip of Sure Status[®] COVID-19 Antigen Card Test



Storage & Stability

Sure Status[®] COVID-19 Antigen Card Test should be stored at 4-30 °C. Do not freeze the kit or components. Extraction Buffer (opened & 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 Extraction buffer beyond the date of expiry.

Shelf Life:

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

Performance Characteristics:

Sure Status[®] COVID-19 Antigen Card Test has 75.23% sensitivity and 98.09% specificity as per ICMR validation Centre.

Operational Characteristics:

Temperature range:

- Sure Status[®] COVID-19 Antigen Card Test is stable at temperature range of 4-30°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 15 to 20 minutes.

Certification:

1. Sure Status[®] COVID-19 Antigen Card Test is WHO EUL approved kit.
2. Sure Status[®] COVID-19 Antigen Card Test is CE-Marked kit.
3. Sure Status[®] COVID-19 Antigen Card Test is manufactured by Premier Medical Corporation Private Limited is ISO 13485 & EN ISO 13485 certified company.

Kit components:

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

- Test devices packed in aluminum pouch with desiccant.
- Nasopharyngeal Swab.
- Extraction Buffer Bottle.
- Reaction Buffer Vial.
- Instructions for use in English language.