



TECHNICAL SPECIFICATION.

Product Name

Sure Status® COVID-19 IgG/IgM 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 IgG/IgM Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	SS02

Intended Use:

Sure Status® COVID-19 IgG/IgM Card Test is single-use lateral flow immunochromatographic assay for the qualitative detection and differentiation of IgG and IgM antibodies against SARS-CoV-2(COVID-19) in human whole blood (Capillary or venous blood), serum and plasma from patients suspected of COVID-19 infection. Sure Status® COVID-19 IgG/IgM Card Test is for in vitro diagnostic use and intended as an aid to the diagnosis of SARS-CoV-2 infection in the convalescent phase of a patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test results and a more specific alternative diagnosis method should be performed to obtain the confirmation of SARS-CoV-2 infections. Negative results do not preclude SARS-CoV-2 infection. Sensitivity of Sure Status® COVID-19 IgG/IgM Card Test early after an infection is not known, as antibodies to SARS-CoV-2 may not be detected in the first few days of infection. False-positive results for Sure Status® COVID-19 IgG/IgM Card Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Positive results must be in conjugation with clinical findings and alternative laboratory tests. 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 mouse anti-human IgG and mouse anti-human IgM antibodies on IgG and IgM labelled test lines. While goat anti-chicken IgY antibody will be used at control line. Colloidal gold coupled with corona virus nucleocapsid antigen or spike protein antigen for test line detection, while chicken IgY will be used control line detection. These coupled colloidal gold along with antigen and antibody will be coupled separately and sprayed on the conjugate pad. Once serum/plasma/whole blood is applied along with the assay buffer they pass through the conjugate pad and bind with antigen coupled colloidal gold, if the specimen contains antibody against corona virus antigen then it will bind with the antigen-colloidal gold complex forming a triple complex of antibody-antigen-colloidal gold. The sample along with formed complexes will migrate through the nitrocellulose membrane by capillary action. The complex of IgG-antigen-

colloidal gold or IgM-antigen-colloidal gold will bind with the respective test lines present on nitrocellulose membrane. If there is no formation of complex the colloidal gold coupled with antigen 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.

Storage & Stability

Sure Status® COVID-19 IgG/IgM Card Test kit should be stored at 4-30°C. Do not freeze the kit or components. The kit is sensitive to humidity and heat. Do not store the kit at temperatures above 30°C and in humid conditions. Assay buffer (opened and unopened) and unopened test device are stable until the expiry date printed on the label when stored at 4-30°C. Perform the test immediately after removing the test device from the aluminum pouch. If a desiccant color has changed from orange to green, do not use the test device. The test device is stable until the printed expiry date on the pouch/external secondary packaging.

Shelf Life:

Sure Status® COVID-19 IgG/IgM Card Test has shelf life of 24 months.

Performance Characteristics:

Sure Status® COVID-19 IgG/IgM Card Test has 100% sensitivity and 99% specificity as per ICMR validation Centre.

Operational Characteristics:

Temperature range:

- Sure Status® COVID-19 IgG/IgM 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:

- Sure Status® COVID-19 IgG/IgM Card Test is a CE-certified product.
- Sure Status® COVID-19 IgG/IgM 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 IgG/IgM Card Test contains:

- Test devices packed in aluminum pouch with desiccant.
- Specimen transfer device
- Assay buffer bottle

- Sterile single-use lancet
- Alcohol swab
- Instructions for use in English language.