WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs
PUBLIC REPORT

Product: Sure Status COVID-19 Antigen Card Test
Manufacturer: Premier Medical Corporation Private Limited
EUL Number: EUL 0590-010-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and the Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Product Dossier Review assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

Sure Status COVID-19 Antigen Card Test, product codes SS03P25 and SS03-NS-P25, Rest of World regulatory version, manufactured by Premier Medical Corporation Private Limited, A1-302, GIDC Sarigam, District, Valsad 396155, India, was listed on 17 March 2021.

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the EUL product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

<table>
<thead>
<tr>
<th>Version</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Addition of nasopharyngeal swabs not included in the product dossier reviewed before listing—inclusion of labels of approved nasopharyngeal swabs in the public report.</td>
<td>4 August 2022</td>
</tr>
<tr>
<td>3.0</td>
<td>Introduction of a new product code SS03-NS-P25 that uses nasal swab specimen type and changes to the sample pad to filter the sticky part of the nasal discharge.</td>
<td>8 November 2022</td>
</tr>
</tbody>
</table>
Intended use:

According to the claim of intended use from Premier Medical Corporation Private Limited, “Sure Status COVID-19 Antigen Card Test is a lateral flow immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal 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 the detection of nucleocapsid protein antigen in a patient with clinical symptoms of SARS-CoV-2 infection. It provides only initial screening test results and a more specific alternative diagnosis method should be performed to obtain the confirmation of SARS-CoV-2 infections. The test is not automated and does not require any additional instrument. The test is designed to be performed by Laboratory professionals/trained users only. The product can be used in a clinical setup and point of care sites that meets the requirements stated in these instructions for use or local regulations.”

Validated specimen type
Nasopharyngeal swab specimens.

Test kit contents

<table>
<thead>
<tr>
<th>Component</th>
<th>25 tests (product code SS03P25)</th>
<th>25 tests (product code SS03-NS-P25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test device pouch containing: test device and desiccant</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Swab</td>
<td>25 (Nasopharyngeal swabs)</td>
<td>25 (Nasal swabs)</td>
</tr>
<tr>
<td>Reaction buffer vial with nozzle</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Extraction Buffer Bottle</td>
<td>3 x 3 mL</td>
<td>5 x 3 mL</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>External Positive Control Swab</td>
<td>\</td>
<td>1</td>
</tr>
<tr>
<td>External Negative Control Swab</td>
<td>\</td>
<td>1</td>
</tr>
</tbody>
</table>

Items required but not provided

- New pair of disposable gloves & facemask;
- Permanent marker pen and Timer;
- PPE Kits;
- Biohazardous waste container.

Storage

4-30°C.

Shelf-life upon manufacture

24 months (real-time stability studies are ongoing).
Warnings/limitations
Refer to the instructions for use (IFU).

Product dossier assessment
Premier Medical Corporation Private Limited submitted a product dossier for the Sure Status COVID-19 Antigen Card Test for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_0347)”. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

Post listing Commitments for EUL:
As commitments to listing, Premier Medical Corporation Private Limited committed to,

1. Participate in the WHO collaborative study to assess the suitability of an interim standard for SARS-CoV-2 virus antigen detection tests.
2. When it becomes available, submit a study report on the estimation of the analytical sensitivity with the WHO International Standard.
3. When this becomes available, submit a study report on the traceability of all relevant materials to the International SARS-CoV-2 virus standard.
4. To submit interim and final stability reports by 30 June 2023.

Risk-benefit assessment conclusion is acceptable.

Quality Management Systems Review
To establish eligibility for WHO procurement, Premier Medical Corporation Private Limited was asked to provide up-to-date information about the status of its quality management system.

Based on the review of the submitted quality management system documentation by WHO staff, it was established that Premier Medical Corporation Private Limited provided sufficient information to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid or antigen (PQDx_347)”.

Quality management system assessment outcome: Acceptable.
Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL listing status:
1. Notification to WHO of any planned changes to a EUL product, in accordance with “WHO procedure for changes to a WHO prequalified in vitro diagnostic” (document number PQDx_121); and

Premier Medical Corporation Private Limited is also required to report complaints related to the product. Specific categories of complaints and changes to the product must be notified immediately to WHO, as per the documents mentioned above.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality and performance monitoring activities are in accordance with WHO guidance “Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics” (ISBN 978-92-4-001531-9).

Scope and duration of procurement eligibility

Sure Status COVID-19 Antigen Card Test, product codes SS03P25 and SS03-NS-P25, manufactured by Premier Medical Corporation Private Limited, is considered eligible for WHO procurement until further notice. The assay may detect the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO-prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, Premier Medical Corporation Private Limited must engage in post-market surveillance activities to ensure that the product meets safety, quality and performance requirements. Premier Medical Corporation Private Limited must notify WHO of any complaints, including adverse events related to the use of the product, within seven days and any changes to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

1 Available on the web page
Labelling

1.0 Labels

2.0 Instructions for Use (IFU)
1.0 Product labels

1.01) Nasopharyngeal Swab Labels

1.02) Nasal Swab Labels
1.03) Extraction Buffer Bottle Label for SS03P25

1.04) Extraction Buffer Bottle Label for SS03-NS-P25

1.05) Reaction buffer nozzle bag label

1.06) Reaction buffer vial bag label
1.07) Negative Control Swab Label for SS03-NS-P25

![Negative Control Swab Label](image)

1.08) Positive Control Swab Label for SS03-NS-P25

![Positive Control Swab Label](image)
1.09) Test Device Pouch

a) Test Device Pouch label for SS03P25
b) Test Device Pouch label for SS03-NS-P25
1.10) Test device
1.11) Outer Box Label
a) Carton label for SS03P25
COVID-19 ANTIGEN CARD TEST
(Nasopharyngeal Swab)

SS03P25
25 Tests/kit
Advanced Quality Screening of COVID-19 Antigen

Contents:
• Individually pouched test devices with desiccant
• Nasopharyngeal swab
• Reaction buffer vial with nozzle
• Extraction Buffer Bottle
• Instructions for use

Mfg. Lic. No.: MFG/MD/2018/000064
LOT: 3 Nos.

Rev. AD, 2021-08
b) Carton label for SS03-NS-P25
COVID-19 ANTIGEN CARD TEST
(Nasal Swab)
SS03-NS-P25
25 Tests/kit
Advanced Quality Screening of COVID-19 Antigen

Contents:
• Individually pouched test devices with desiccant
• Nasal swab
• Reaction buffer vial with nozzle
• Extraction Buffer Bottle
• Positive control swab
• Negative control swab
• Instructions for use

FOR EXPORT ONLY
3.0 Instructions for use²

² English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
a) Instructions for Use of SS03P25
A study was performed to demonstrate that potentially interfering substances that could potentially cross-react with the Sure Status® COVID-19 Antigen test do not cross-react or interfere with the detection of SARS-CoV-2 (COVID-19) when tested in the absence or presence of SARS-CoV-2 at 67.2-70% RH. The study included the testing of various microorganisms, viruses, and negative matrices.

### Materials Provided

<table>
<thead>
<tr>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngeal swab</td>
<td>25 Nos.</td>
</tr>
<tr>
<td>Extraction buffer solution</td>
<td>25 Nos.</td>
</tr>
<tr>
<td>Individual pouch test device</td>
<td>25 Nos.</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>1 No.</td>
</tr>
<tr>
<td>Permanent marker pen and timer</td>
<td>1 No.</td>
</tr>
<tr>
<td>Biohazardous waste container</td>
<td>1 No.</td>
</tr>
<tr>
<td>Nasal gel medicine</td>
<td>1 Box</td>
</tr>
<tr>
<td>Antiviral drug</td>
<td>1 Box</td>
</tr>
<tr>
<td>Allergy</td>
<td>1 Box</td>
</tr>
</tbody>
</table>

### Study Design

Each sampling and extraction was taken to be representative of the whole specimen. The Sure Status® COVID-19 Antigen Card Test was performed by a trained individual according to the instructions for use. The samples were evaluated in triplicate in the absence or presence of SARS-CoV-2 at 67.2-70% RH. The results were evaluated by a trained individual using the Sure Status® COVID-19 Antigen Card Test and were recorded as either reactive or non-reactive. The results were evaluated by a trained individual using the Sure Status® COVID-19 Antigen Card Test and were recorded as either reactive or non-reactive.

### Results

No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below:

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Coronavirus (A/Brisbane/59/2007)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (A/Japan/1/2001)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (A/WHO/386/2004)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (A/New York/1/2005)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (A/Beijing/66/2008)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (A/Peru/31/2009)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (A/Hong Kong/1/2021)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (A/Hong Kong/2/2021)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (B/Florida/4/2014)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (B/Florida/4/2014)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
<tr>
<td>Human Coronavirus (B/WHO/2/2003)</td>
<td>1.0 x 10^5 PFU/mL</td>
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<tr>
<td>Human Coronavirus (B/WHO/2/2003)</td>
<td>1.0 x 10^5 PFU/mL</td>
</tr>
</tbody>
</table>

Other substances tested include:

- Human Metapneumovirus (hMPV) | 1.0 x 10^5 TCID50/ml |
- Parainfluenza virus Type 1 | 1.0 x 10^5 TCID50/ml |
- Parainfluenza virus Type 2 | 1.0 x 10^5 TCID50/ml |
- Chlamydia pneumoniae | 1.0 x 10^6 CFU/mL |
- Mycoplasma pneumoniae | 1.0 x 10^6 CFU/mL |
- MERS-CoV | 1.0 x 10^6 IFU/mL |
- SARS-CoV | 1.0 x 10^6 PFU/mL |
- Human adenovirus | 1.0 x 10^6 PFU/mL |
- Human rhinovirus | 1.0 x 10^6 PFU/mL |
- Human influenza A virus | 1.0 x 10^6 PFU/mL |
- Human influenza B virus | 1.0 x 10^6 PFU/mL |
- Human influenza C virus | 1.0 x 10^6 PFU/mL |
- Herpes simplex virus | 1.0 x 10^6 PFU/mL |
- Varicella zoster virus | 1.0 x 10^6 PFU/mL |
- Epstein-Barr virus | 1.0 x 10^6 PFU/mL |
- Human papillomavirus | 1.0 x 10^6 PFU/mL |
- Human herpesvirus | 1.0 x 10^6 PFU/mL |
- Human herpesvirus | 1.0 x 10^6 PFU/mL |
- Human herpesvirus | 1.0 x 10^6 PFU/mL |
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### Limitations

1. In vivo results should be treated as an indication of the potential activity of the test device and should not be interpreted as indicative of the clinical significance of the result. Positive results should be confirmed by an additional test, such as culture or molecular testing for SARS-CoV-2.
2. False-positive results may occur in the absence or presence of SARS-CoV-2. False-negative results may be obtained in the absence or presence of SARS-CoV-2.
3. False-positive results may occur in the absence or presence of SARS-CoV-2. False-negative results may be obtained in the absence or presence of SARS-CoV-2.

### Storage and Stability

The Sure Status® COVID-19 Antigen Card Test is for in vitro diagnostic use and intended as an aid in the diagnosis of SARS-CoV-2 in patients with symptoms consistent with COVID-19. The Sure Status® COVID-19 Antigen Card Test is for use in patients aged 18 years and older. It is not intended for use in children or patients under the age of 18 years.

### Instructions for Use

1. Ensure that the test device is sealed and unopened.
2. Remove the plastic bag from the test device.
3. Open the test device by removing the cover and exposing the test strip.
4. Apply the test device to the specimen by placing it on the specimen.

### Negative Matrix Study

No cross-reactivity or interference was seen with the following negative matrices:

- Human sera
- Human urine
- Human stool
- Human saliva
- Human oral fluid
- Human blood
- Human sputum

### Notes

1. Other substances (Biotin, HAMA, and Rheumatoid factor) were tested with 70 TCID50/swab.
2. Sodium hydroxide 0.1% w/v.
3. Phenol 10% v/v.
4. Dexamethasone 0.1% w/v.

### Conclusion

The Sure Status® COVID-19 Antigen Card Test is for in vitro diagnostic use and intended as an aid in the diagnosis of SARS-CoV-2 in patients with symptoms consistent with COVID-19. The Sure Status® COVID-19 Antigen Card Test is for use in patients aged 18 years and older. It is not intended for use in children or patients under the age of 18 years.

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### References


### Endocarditis

50% of endocarditis cases are caused by amoxicillin-resistant Staphylococcus aureus (MRSA) and 50% are caused by gram-negative bacteria. The study included the testing of various microorganisms, viruses, and negative matrices.

### Cross-reactivity and Interference Study

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**TEST PROCEDURE (PICTORIAL PRESENTATION)**

1. **Nasopharyngeal Swab Collection**
   - Tilt patient’s head back 15 degrees. Insert a 4-inch sterile drape into the nasal cavity of the patient, swab over the surface of the posterior nasopharynx. (Swab should reach depth equal to distance from nostrils to parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.)

2. **Internal Quality Control**
   - Specimen may be stored at 4°C (39°F) for up to 3 days. Specimens should be transported to the laboratory in a biohazardous waste container.

3. **Test Procedure**
   - Open the device pouch, take out the test device from the aluminum pouch. Do not remove the cap. The test device is disposable. The test device should be used only once. Never reuse the test device.

   - Insert the Swab Specimen in the reaction buffer vial and swirl the swab 5-10 times.

   - Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used Nasopharyngeal Swab as biohazardous waste.

   - Close the reaction buffer vial firmly by pressing.

   - Open the device pouch, take out the test device from the aluminum pouch. Do not remove the cap. The test device is disposable. The test device should be used only once. Never reuse the test device.

   - Insert the Swab Specimen in the reaction buffer vial and swirl the swab 5-10 times.

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   - Close the reaction buffer vial firmly by pressing.

4. **Analysis**
   - Insert using the procedure appropriate for patient nasopharyngeal swab specimens. Perform a new test device.

   - TCID50 / mL of gamma-irradiated SARS-CoV-2 with the Sure Status® COVID-19 antigen rapid test was established using limiting dilutions of genomic RNA from an isolate of SARS-CoV-2 (NCP-HD021). The SARS-CoV-2 viral particles were dispersed in PBS (supplemented with 0.05% Tween-20) and ethanol and maintained in a critical level of activity. The Sure Status® COVID-19 antigen rapid test was evaluated in this natural nasal swab matrix pool to obtain the different viral dilutions required for the study. Continued nasal swab samples were prepared by adding 60 µl of each of the viral dilutions into the swab. The swabs were then frozen according to the testing schedule.

5. **Limit of Detection (Analytical Sensitivity)**
   - Limit of Detection (LOD) studies determine the lowest communicable concentration of SARS-CoV-2 at which 100% of all true positive samples test positive. The LOD in the Sure Status® COVID-19 antigen rapid test was established using limiting dilutions of genomic RNA from an isolate of SARS-CoV-2 (NCP-HD021). The SARS-CoV-2 genomic RNA was dispersed in PBS (supplemented with 0.05% Tween-20) and ethanol and maintained in a critical level of activity. The Sure Status® COVID-19 antigen rapid test was evaluated in this natural nasal swab matrix pool to obtain the different viral dilutions required for the study. Continued nasal swab samples were prepared by adding 60 µl of each of the viral dilutions into the swab. The swabs were then frozen according to the testing schedule.

6. **Performance Characteristics**
   - Clinical performance characteristics of the Sure Status® COVID-19 Antigen Card Test were evaluated in a USF and India. The study was carried out at different sites in the USF (Florida) and India. The Sure Status® COVID-19 Antigen Card Test was evaluated by comparing the results obtained with the comparator method (Sure Status® COVID-19 Antigen Card Test) against the comparator method (Sure Status® COVID-19 Rapid Antigen Test). The Sure Status® COVID-19 Antigen Card Test was found to be valid in detecting the different viral dilutions required for the study. The results obtained were compared with the comparator method (Sure Status® COVID-19 Rapid Antigen Test). The Sure Status® COVID-19 Antigen Card Test was found to have a specificity of 100% and a sensitivity of 98.5%.

7. **High Dose Hook Effect**
   - The Sure Status® COVID-19 Antigen Card Test exhibits an hook effect at high concentrations of SARS-CoV-2 genomic RNA. This effect is observed when very high levels of a target are present in a sample matrix. To determine if Sure Status® COVID-19 Antigen Card Test exhibits any high dose hook effect, increasing concentrations of genomic RNA (ranging from 2.5 x 10^9 to 2 x 10^10 copies per mL) were tested in a concentration of 2.5 x 10^9 to 2 x 10^10 copies per mL. For this study, the Sure Status® COVID-19 Antigen Card Test was found to exhibit a “hook” effect at high concentrations of genomic RNA (ranging from 2.5 x 10^9 to 2 x 10^10 copies per mL). This effect was observed at high concentrations of genomic RNA (ranging from 2.5 x 10^9 to 2 x 10^10 copies per mL).
b) Instructions for Use of SS03-NS-P25
**INTENDED USE**

Sure Status® COVID-19 Antigen Card Test (Blood-based) is a lateral flow immunochromatographic assay for qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human blood. This is intended for use in the diagnosis of suspected cases of COVID-19 in adults and children (≥ 3 years old). For in vitro use.

**EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED**

- Nasal swab, if necessary
- Extraction Buffer Bottle (opened and unopened) & the unopened test device are required.

**MATERIALS PROVIDED**

- Sure Status® COVID-19 Antigen Card Test (Blood-based)
- Extraction Buffer Bottle
- Sure Status® COVID-19 Antigen Card Test (Blood-based)

**DIAGNOSIS**

This test cannot rule out diseases caused by other bacterial or viral pathogens.

**SPECIMEN COLLECTION**

- Nasal swab:
  - Use only provided or recommended Nasal swab for specimen collection.
  - Process the test sample immediately after collection.
  - Do not re-use the test device, Nasal swab and reaction buffer vial with nozzle as these are for single use only.
  - Do not smoke, eat or drink while handling specimens and performing a test.

**WARNING**

- Do not handle the kit or components
- Do not store the kit at temperatures above 40°C.

**STORAGE AND HANDLING**

- Do not freeze the kit or components.
- This test cannot be used for nasopharyngeal swabs.
- This test cannot be used for throat swabs.

**PRESERVATION**

- Specimen preservation is not required.

**PRECAUTIONS**

- Specimen preservation is not required.

**EXTRACTED MATERIALS**

- SARS-CoV-2 Antigen in Human Nasal Swab.

**INTENDED USE**

Sure Status® COVID-19 Antigen Card Test (Blood-based) is a lateral flow immunochromatographic assay for qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human blood. This is intended for use in the diagnosis of suspected cases of COVID-19 in adults and children (≥ 3 years old). For in vitro use.

**MATERIALS PROVIDED**

- Sure Status® COVID-19 Antigen Card Test (Blood-based)
- Extraction Buffer Bottle
- Sure Status® COVID-19 Antigen Card Test (Blood-based)

**DIAGNOSIS**

This test cannot rule out diseases caused by other bacterial or viral pathogens.

**SPECIMEN COLLECTION**

- Nasal swab:
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- Extraction Buffer Bottle
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- Specimen preservation is not required.

**PRECAUTIONS**

- Specimen preservation is not required.

**EXTRACTED MATERIALS**

- SARS-CoV-2 Antigen in Human Nasal Swab.

**INTENDED USE**

Sure Status® COVID-19 Antigen Card Test (Blood-based) is a lateral flow immunochromatographic assay for qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human blood. This is intended for use in the diagnosis of suspected cases of COVID-19 in adults and children (≥ 3 years old). For in vitro use.

**MATERIALS PROVIDED**

- Sure Status® COVID-19 Antigen Card Test (Blood-based)
- Extraction Buffer Bottle
- Sure Status® COVID-19 Antigen Card Test (Blood-based)

**DIAGNOSIS**

This test cannot rule out diseases caused by other bacterial or viral pathogens.

**SPECIMEN COLLECTION**

- Nasal swab:
  - Use only provided or recommended Nasal swab for specimen collection.
  - Process the test sample immediately after collection.
  - Do not re-use the test device, Nasal swab and reaction buffer vial with nozzle as these are for single use only.
  - Do not smoke, eat or drink while handling specimens and performing a test.

**WARNING**

- Do not handle the kit or components
- Do not store the kit at temperatures above 40°C.

**STORAGE AND HANDLING**

- Do not freeze the kit or components.
- This test cannot be used for nasopharyngeal swabs.
- This test cannot be used for throat swabs.

**PRESERVATION**

- Specimen preservation is not required.

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**EXTRACTED MATERIALS**

- SARS-CoV-2 Antigen in Human Nasal Swab.
TEST PROCEDURE (PICTORIAL PRESENTATION)

1. **Nasal Swab Collection**
   - Tilt patient’s head back 70 degrees. With gentle rotating the swab, introduce the swab into a nostril parallel to the palate until resistance is met at the turbinates.

2. **Buffering**
   - Rotate the swab several times against nasal wall.

3. **Extraction**
   - Invert the reaction buffer vial and gently squeeze it to draw 3 drops of specimens nozzle to extract the liquid from the swab.
   - Remove swab, insert it into the other nostril and repeat the process.

4. **Incorporation into Buffer**
   - Collect the Nasal Swab specimen with extraction buffer into reaction buffer vial. Close the nozzle cap tightly onto the vial before gently squeezing the vial. Remove the swab while squeezing the nozzle to avoid liquid escape.

5. **Incubation**
   - Close the reaction vial tightly with the cap.

6. **Visualization**
   - Leave the reaction vial for 20 minutes.

HOW TO INTERPRET TEST RESULTS

**POSITIVE RESULTS**
- In addition to the presence of the C line, if the T line doesn’t appear, the test indicates the presence of SARS-CoV-2 Antigen.

**NEGATIVE RESULTS**
- No presence of control line ‘C’ in the results indicate an invalid result.
- If only a single line appears, at control line ‘C’, as in the figure, the test indicates the absence of SARS-CoV-2 Antigen.

**INVALID RESULTS**
- If no lines appear, or if the lines form outside the device and are not visible, the result is invalid.
- The test results should be retested with a new test device.

**CLINICAL PERFORMANCE**

Climical performance characteristics of Sure Status® COVID-19 Antigen Card Test (Nasal Swab) were evaluated in India. The study was carried out in 2 different sites. Testing was performed by qualified operators having laboratory experience. An FDA, Emergency Use Authorization Test (Sure Status® COVID-19 Antigen Card Test (Nasal Swab)) was performed for 176 positive nasal swab specimens having Ct value >30.

<table>
<thead>
<tr>
<th>Antigen Test (Sure Status® COVID-19 Antigen Card Test (Nasal Swab))</th>
<th>Comparator Method (Real-time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>90.34%</td>
</tr>
<tr>
<td>Specificity</td>
<td>99.79%</td>
</tr>
<tr>
<td>Positive Predictive Value</td>
<td>95.34%</td>
</tr>
<tr>
<td>Negative Predictive Value</td>
<td>99.53%</td>
</tr>
</tbody>
</table>

**LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)**

Limit of Detection (LOD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of false positive replaces true positive. The LOD for the Sure Status® COVID-19 Antigen Card Test (Nasal Swab) was determined using the comparator method for this study. Calibration runs were performed at 10, 100, 1,000, 10,000 and 100,000 TCID50/ml of gamma-irradiated SARS-CoV-2 with the Sure Status® COVID-19 Antigen Card Test (Nasal Swab) as per the Product Insert using the procedure appropriate for patient nasal swab collection.

<table>
<thead>
<tr>
<th>TCID50/ml</th>
<th>Sure Status® COVID-19 Antigen Card Test (Nasal Swab)</th>
<th>Comparator Method (RT-PCR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>100</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>1,000</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>10,000</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>100,000</td>
<td>Positive</td>
<td>Positive</td>
</tr>
</tbody>
</table>

**HIGH DOSE HOOK EFFECT**

No impact on test performance or high dose hook effect was observed up to 2.8 x 105 TCID50/swab.

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Sure Status® COVID-19 Antigen Card Test (Nasal Swab)</th>
<th>Comparator Method (RT-PCR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Negative</td>
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