REF SS03 DO NOT USE VTM COLLECTED SPECIMEN FOR FIELD TESTING.

Sure Status® COVID-19 Antigen Card Test Guideline — Rapid Diagnostic Test for Detection of SARS-CoV-2 Antigen

Guidelines for Testing

IVD 4°C 30°C

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.

IMPORTANT!

Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information.
Note: Specimen should be tested as soon as possible after collection. Specimens may be stored at room temperature for up to 1 hours prior to testing.

General Guidance Antigen Testing for SARS-CoV-2

Do not use test device on VTM as this is not validated with our test and suggested to use extraction buffer provided with the kit.

- Sure Status® COVID-19 Antigen Card Test is currently authorized to be performed on nasopharyngeal swab only.
- Performance of antigen tests can be affected if the test components are not stored and handled properly. They should never be frozen and should always be allowed to reach room temperature (15-30°C) before use. The package insert for these test includes instructions for handling of the test card, follow the complete process as mentioned in the IFU. Reading the test before or after the specified time could result in false positive or false negative test results.
- Processing multiple specimens successively or in batch mode may increase the risk of contamination and may make it more challenging to ensure that each specimen is incubated for the correct amount of time before the result is read. Refer to the package insert for the correct incubation time for that test, and then monitor and ensure proper timing for each specimen during testing and when reading results.
- All testing for SARS-CoV-2, including antigen testing, depends on the integrity of the specimen, which is affected by procedures for both specimen collection and handling. Improper specimen collection, such as swabbing the nostril too quickly, may cause insufficient specimen collection, resulting in limited amounts of viral genetic or antigenic material for detection. Time from specimen collection to testing should be minimized, and the temperature of the specimen during this time must be controlled.
- Proper procedures should be followed to prevent cross-contamination and inaccurate test results. If antigen testing returns multiple unexpected positive results, it may be appropriate to stop testing patient specimens, review all procedures, clean all surfaces, change gloves, and immediately inform to Premier Medical Corporation Private Limited. In such circumstances, confirmatory testing should be considered for people who received unexpected results, regardless of pretest probabilities.
- Clean work surfaces and equipment regularly (daily or as often as needed) with soap or detergent. If regular disinfection is needed, use an EPA-approved disinfectant for SARS-CoV-2.
- Gloves should be changed before collecting, handling, and processing a new specimen in the antigen test system. Failing to change gloves can increase the risk of cross-contamination and false antigen test results.
- Proper interpretation of antigen test results is important for accurate clinical management of patients or people with suspected COVID-19, or for identification of infected people when used for screening. The clinical performance of diagnostic tests largely depends on the circumstances in which they are used. Both antigen tests and NAATs perform best if the person is tested when their viral load is generally highest. Because antigen tests perform best in symptomatic people and within a certain number of days since symptom onset, antigen tests are used frequently on people who are symptomatic. Antigen tests also may be informative in diagnostic testing situations in which the person has a known exposure to a person with COVID-19.
- Antigen tests have been used for screening testing in high-risk congregate housing settings, such as nursing homes, in which repeat testing has quickly identified people with COVID-19, informing infection prevention and control measures, thus preventing transmission. In this case, and where rapid test turnaround time is critical, there is value in providing immediate results with antigen tests, even though they may have lower sensitivity than NAATs.

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- Antigen tests for SARS-CoV-2 are generally less sensitive than real-time reverse transcription polymerase chain reaction (RT-PCR) and other nucleic acid amplification tests (NAATs) for detecting the presence of viral nucleic acid.
- Healthcare providers and public health practitioners should understand test performance characteristics to recognize potentially false negative or false positive test results and to guide additional confirmatory testing and management of the patient or person.
- Positive and negative predictive values of all in vitro diagnostic tests (e.g., NAAT and antigen tests) vary depending upon the pretest probability. Pretest probability considers both the prevalence of the target infection in the population that is being tested as well as the clinical context of the individual being tested.

Do's

- Bring the Sure Status® COVID-19 Antigen Card Test kit components to room temperature(15°C to 30°C) prior to testing.
- Label the test device with the patient identification number. Place the test device on a flat, clean, and dry surface.
- Fill the reaction buffer vial upto the embossed marking or add 12 drops (Approx 300 µl) of extraction buffer into reaction buffer vial.
- Swirl the swab 5-10 times.
- Close the nozzle cap tightly onto the reaction buffer vial by pressing. Add the exactly 3 drops of extraction buffer as there is a possibility of False Positive results when insufficient extraction buffer is used in the test.
- If test window(Background) is not clear at 15 minutes then read the result at 20 minutes.
- After recording the results, dispose of the test device and remaining reaction buffer vial solution as biohazardous waste.

Don'ts

- Do not use the test device if the desiccant color has changed from orange to green.
  Do not use instantly remove the swab from the reaction buffer vial.
- Do not use the VTM collected specimen as this is not validated and approved to be used with Sure Status® COVID-19 Antigen Card Test.
- Do not add more or less than 12 drops into the reaction buffer vial.
  Do not dispense more or less than 3 drops of exctraction buffer into the specimen well.
- Do not interpret after 20 minutes.
- Do not reuse any of the test components provided.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.
- Do not use the other than human specimen.

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SPECIMEN COLLECTION AND HANDLING

STEP 1

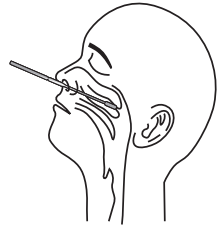
Take extraction buffer bottle provided, twist open the cap and add 12 drops (Approx 300 µl) or fill the vial upto the embossed marking of extraction buffer into reaction buffer vial.

Marking at approx 300µl ⟶

STEP 2

Tilt patient's head back 70 degrees. Insert a (Minitip) sterile swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. (Swab should reach depth equal to distance from nostrils to outer opening of the ear).

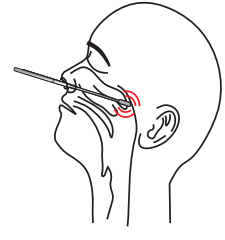
Nasopharyngeal Swab Collection.



STEP 3

Slowly rotate swab (right and left) in nostril to absorb secretions. Slowly remove swab after rotating it.

Nasopharyngeal Swab Collection.



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Follow the WHO/US CDC Universal Precautions for the safety against Novel Corona Virus (SARS-CoV-2).

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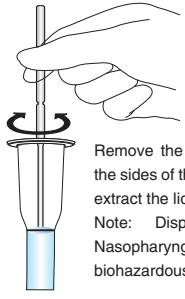
PROCEDURE

STEP 4

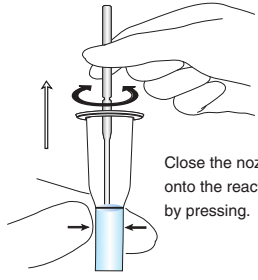
Insert the swab into reaction buffer vial. Swirl the swab 5-10 times.

STEP 5



Remove the swab while squeezing the sides of the reaction buffer vial to extract the liquid from the swab.
Note: Dispose of the used Nasopharyngeal Swab as biohazardous waste.

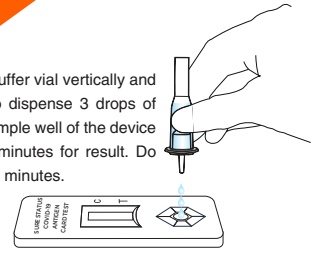
STEP 6



Close the nozzle cap tightly onto the reaction buffer vial by pressing.

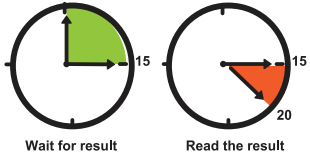
STEP 7

Invert the reaction buffer vial vertically and gently squeeze it to dispense 3 drops of specimens into a sample well of the device and wait for 15-20 minutes for result. Do not interpret after 20 minutes.



Note: *If test window(Background) is not clear at 15 minutes then read the result at 20 minutes.*

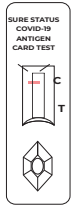
10 Results



Wait for result | Read the result

INTERPRETATION

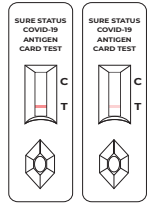
STEP 5 : Read Results



If only a single line appears, at control line "C" as in the figure, the test indicates the absence of SARS-CoV-2 Antigen.

The result is Negative or non-reactive.

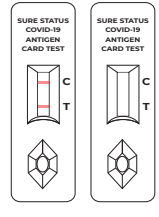
NEGATIVE



In addition to the presence of the C line, if the T line develops, the test indicates the presence of SARS-CoV-2 Antigen. The result is positive or reactive.

Note: Interprete faint line as reactive line. Alternative diagnosis method should be performed in order to obtain the confirmation of SARS-CoV-2 infections.

POSITIVE



No presence of control line 'C' in the results window (irrespective of presence of test lines) indicates an invalid result.
The directions may not be followed correctly or the test may have deteriorated.
The Invalid test results should be retested with new test device.

INVALID

Manufactured by

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