REF SS03

Quick Reference Instructions for Sure Status® COVID-19 Antigen Card Test

Rapid Diagnostic Test for Detection of SARS-CoV-2 Antigen

JOB AID

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.

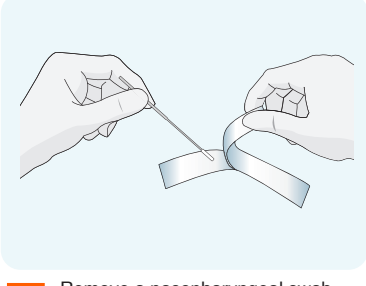
IMPORTANT!

Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.

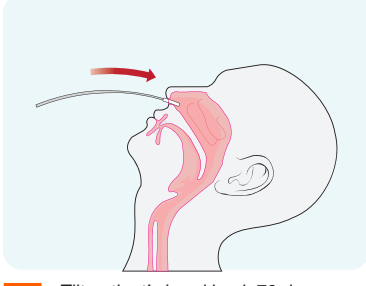
Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information.

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.

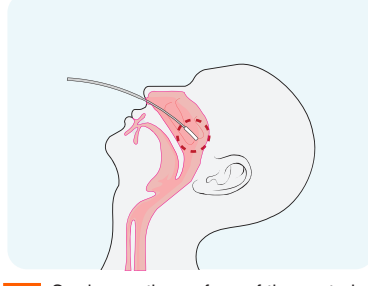
SPECIMEN COLLECTION AND HANDLING



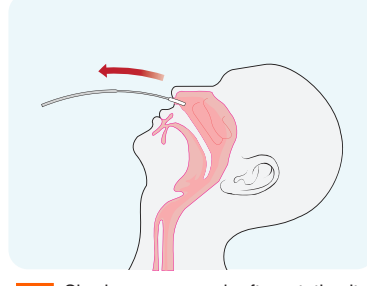
1 Remove a nasopharyngeal swab from the pouch.



2 Tilt patient's head back 70 degrees. Insert a (Minitip) sterile swab into the nostril of the patient.



3 Swab over the surface of the posterior nasopharynx. (Swab should reach depth equal to distance from nostrils to outer opening of the ear). Slowly rotate swab (right and left) in nostril to absorb secretions.



4 Slowly remove swab after rotating it.

Manufactured by

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INSTRUCTIONS FOR USE

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

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

DO NOT USE VTM COLLECTED SPECIMEN FOR FIELD TESTING.

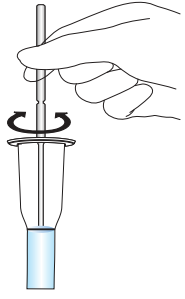
PROCEDURE

STEP 5

Embossed marking at → approx 300µl

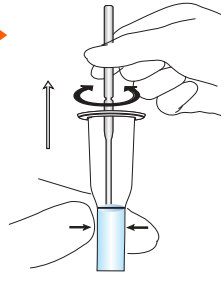
Take extraction buffer bottle provided, twist open the cap and fill the reaction buffer vial upto the embossed marking or add 12 drops (Approx 300 µl) of extraction buffer into reaction buffer vial.

STEP 6



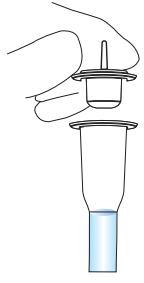
Insert the swab into reaction buffer vial. Swirl the swab 5-10 times.

STEP 7



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.

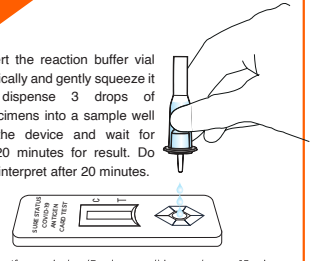
STEP 8



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

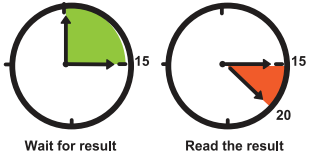
STEP 9

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.*

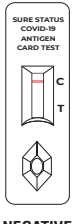
9 Results



Wait for result | Read the result

INTERPRETATION

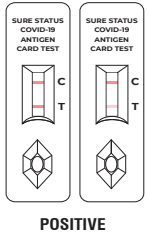
Read Results



NEGATIVE

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

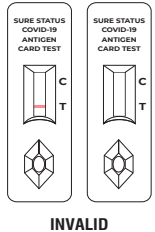
The result is Negative or non-reactive.



POSITIVE

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.



INVALID

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 detoriorated.
The Invalid test results should be retested with new test device.