

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

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

INTENDED USE

The Sure Status® COVID-19 Antigen Card Test (Home test) is a single-use, in vitro (outside the body) visually read rapid immunoassay that uses a human nasal swab specimen for the qualitative detection of nucleocapsid protein SARS-CoV-2 antigen (Ag). The Sure Status® COVID-19 Antigen Card Test (Home test) is intended to be used manually by untrained lay users (self testing) aged 18 years or above in a private setting to aid in the diagnosis of an active SARS-CoV-2 infection. Adults can collect nasal swab specimens from individuals aged 2-17 years who are suspected of COVID-19.

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 according to local guidelines. Refer to the product insert disposal information.

Note: Extract the specimen immediately (within 5 min.) after the collection from the nostril to avoid the contamination. Perform the testing immediately (within 5 min) after the extraction of specimen into the pre-filled reaction buffer vial.

Before you start



Wash your hands.
Make sure they are dry before starting the test.

Take out the Kit Components



BOPP Pouch Containing all kit components

Carton

Individual Kit components illustration



Remove the BOPP pouch from the kit and then remove test components from the BOPP pouch and place them on a **flat** and **dry** surface.

Step 1: Initiation of Testing

Remove the test device from the pouch

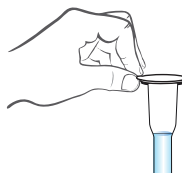


Desiccant Validity

● Orange: Valid

● Green (Do not use the test device if the desiccant turns green).

Peel off aluminium foil from pre-filled tube.

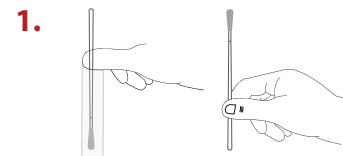


Push the buffer tube on to the **perforated vial stand** (back side of the carton).



Step 2: Specimen Collection

1.



Remove the Nasal Swab from the pouch



Do not touch the tip of the swab.



2.

Insert the swab into right nostril (about 2-3 cm) or until resistance is felt.



3.

Slowly rotate the swab, while gently rubbing it along the nasal passage for minimum of 5 times.



4.

Take out the swab from right nostril Insert the swab into left nostril (about 2-3 cm) or until resistance is felt.



5.

Slowly rotate the swab, while gently rubbing it along the nasal passage for minimum of 5 times.





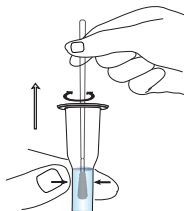
PROCEDURE

1.



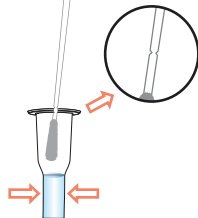
Insert the swab into tube and swirl the swab **5-10 times**.

2.



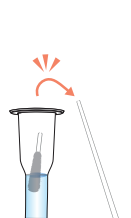
Pinch the swab tip through the Tube to extract any remaining fluid.

3.



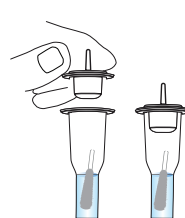
Hold the buffer tube firmly, lift the swab till breakpoint and snap the swab handle at **breakpoint**.

4.



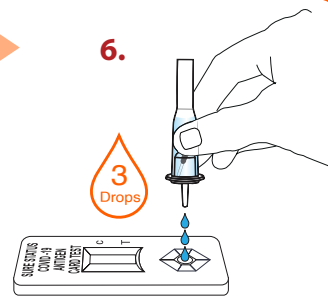
Leave the swab inside the tube and discard the stick.

5.



Secure the Nozzle on the tube.

6.



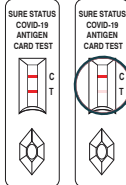
Invert the tube and gently squeeze it to dispense **3 drops** of specimens into a specimen well.

Step 4: Result Interpretation

Read the results within **15-20 minutes**.
Do not read after **20 minutes**.



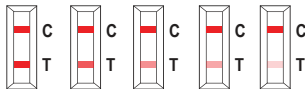
Positive Result



If both Control line "C" and Test line "T" appear, the result is **Positive**.

Look very closely! Even a **faint line** indicates a positive results.

Different possibilities of a positive results.



Note: Positive results may indicate SARS-CoV-2 infection. Follow national guidelines for home isolation and care.

Negative Result

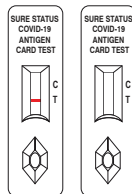


If there is only Control line "C" and no Test line "T" visible, the result is **Negative**.

Note: Test results negative and still having symptoms ??? Confirm the results with a confirmatory or more sensitive test (RT-PCR).

All RAT negative symptomatic individuals may be treated as suspect COVID-19 cases and are advised to follow national guidelines for home isolation protocol while awaiting the RT-PCR test results.

Invalid Result



If the Control line "C" is not visible, the results will be **Invalid** regardless of presence of Test line "T".

Invalid Test should be retested with fresh device.

Disposal of Test Kit

Swab inserted in the vial filled with liquid kills the Corona virus. Pack the used components in the disposal bag, and throw it to waste bin.

Disinfect all surfaces that the specimen may have touched, and wash your hands thoroughly afterwards.



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