



COVID-19 Antigen Rapid Self-Test Kit

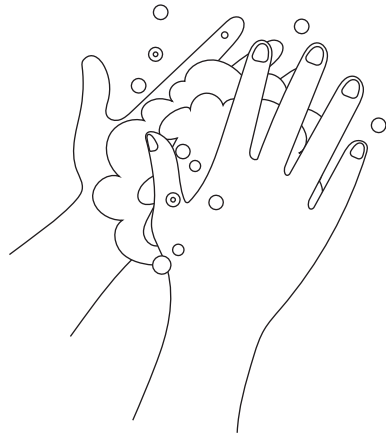
USER INSTRUCTIONS

MATERIALS PROVIDED

- 2 Test Pouches each containing one Test Card
- 2 Antigen Extraction Tubes filled with buffer
- 2 Sterile Swabs
- 2 Ziplock Bags
- 1 Instructions for use

STEP 1

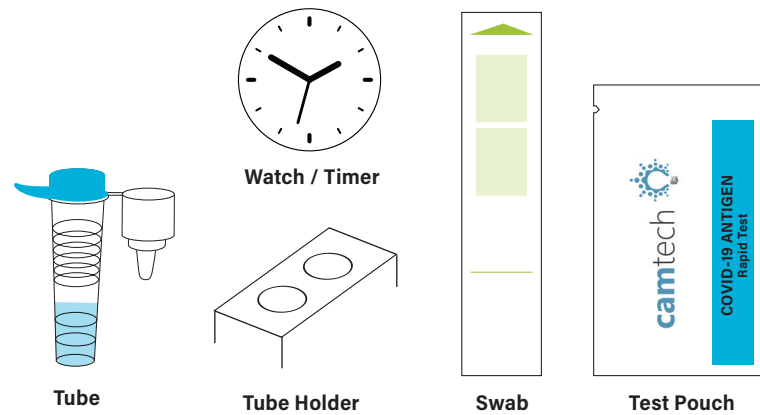
Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.



STEP 2

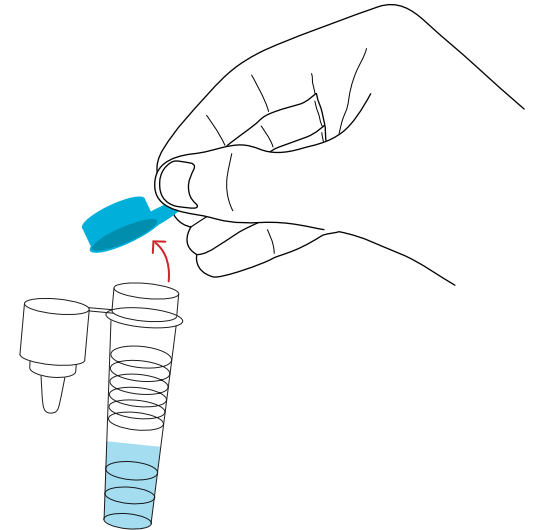
Take out the test pouch and other provided materials and lay them on the table to prepare for use.

Perform the test at room temperature and 30%-50% humidity for best results.



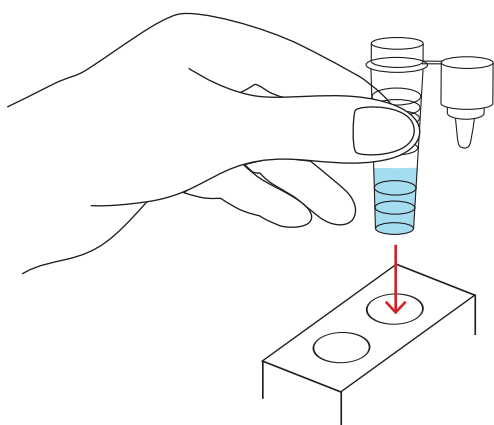
STEP 3

Remove cap from one of the tubes and discard the cap.



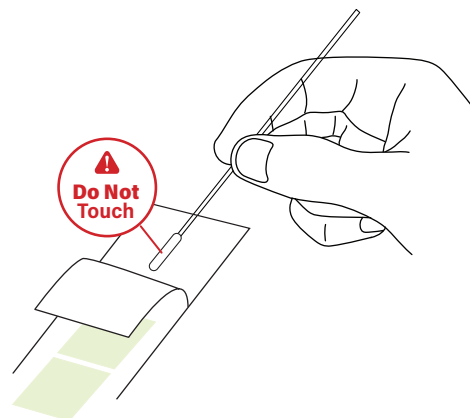
STEP 4

Place tube in the tube holder.
(Use of gloves is recommended)



STEP 5

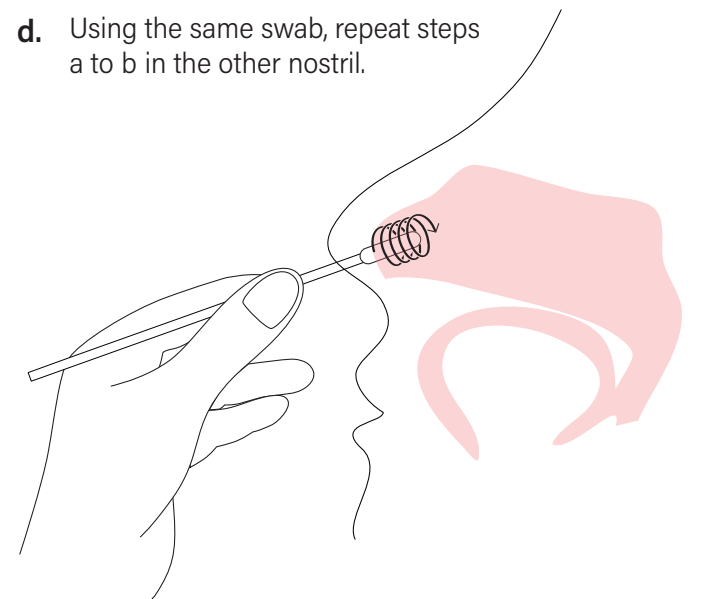
Remove the swab from its wrapper, being careful not to touch the soft end, which is the absorbent tip.



STEP 6

Swab the Nostrils

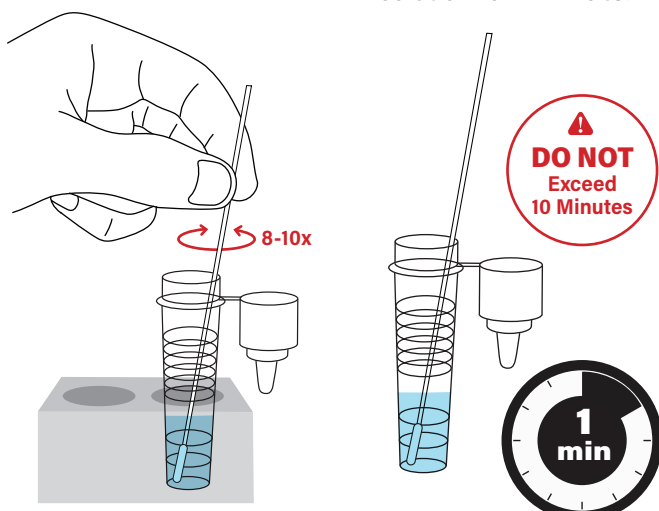
- Insert the entire absorbent tip of the swab into the nostril, but do not insert the swab more than $\frac{3}{4}$ of an inch (1.5 cm) into the nose.
- Slowly rotate the swab in a circular path against the inside of the nostril at least **4 times** for a total of **15 seconds**. Be sure to collect any nasal secretion that may be present on the swab.
- Gently remove the swab.
- Using the same swab, repeat steps a to b in the other nostril.



STEP 7

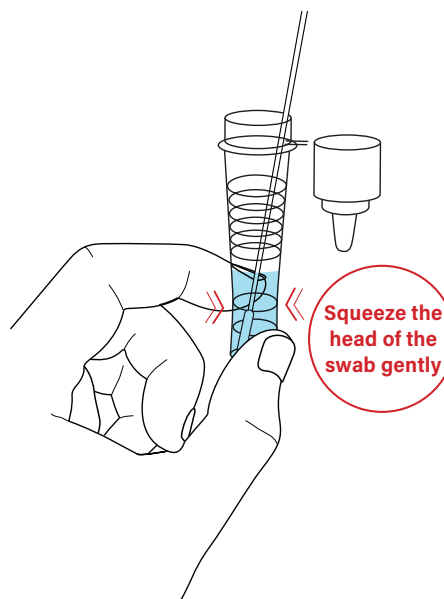
Place Swab in the Tube

- Immediately place the swab into the liquid inside the tube, and ensure it is touching the bottom of the tube.
- Stir 8 - 10 times.
- Leave the swab in the solution for **1 minute**.



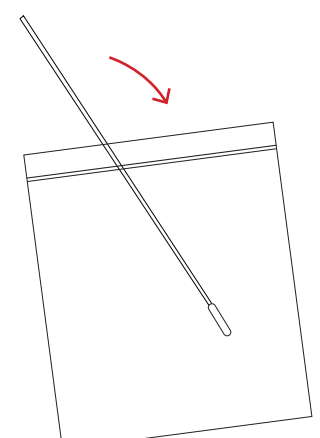
STEP 8

After one minute, Remove the swab while **squeezing wall of the tube** against the swab while rotating the swab, to extract the nasal secretions from the swab.



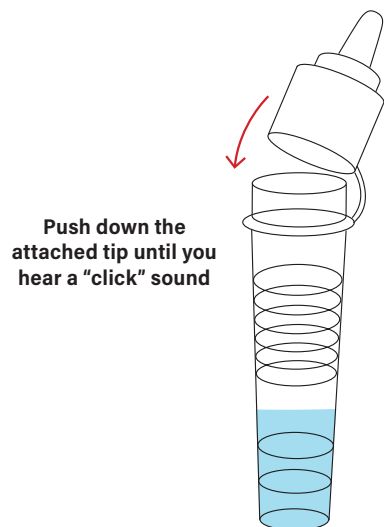
STEP 9

Dispose the swab in the disposable ziplock bag provided.



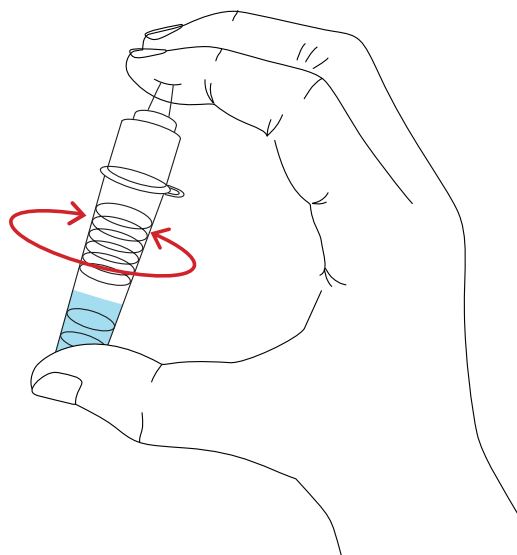
STEP 10

Close up the tube firmly using attached tip.



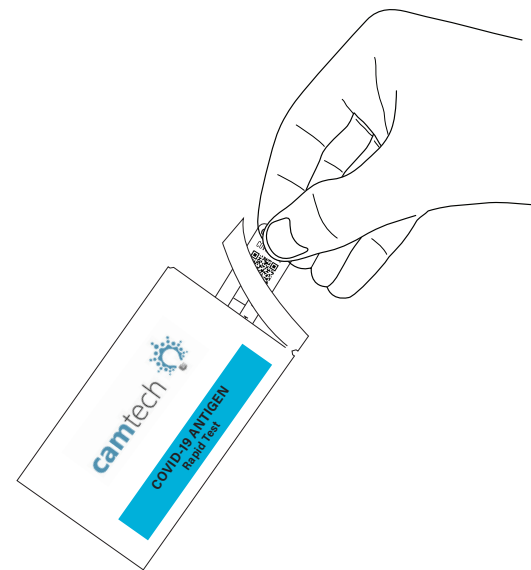
STEP 11

Mix thoroughly by flicking the bottom of the tube.



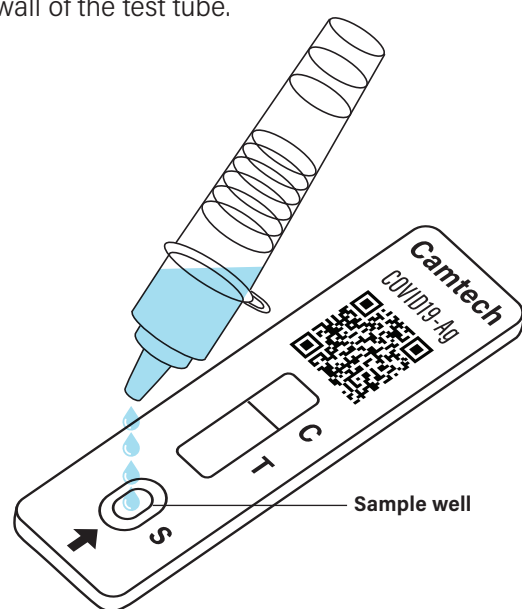
STEP 12

Take out the test card from the test pouch.



STEP 13

Hold the tube vertically and **squeeze 4 drops** of the solution onto the sample well (S) of the test card by squeezing the wall of the test tube.



STEP 14

Wait for **15 minutes** after adding the sample solution into the well of the test card and interpret the results. **Do not evaluate the result more than 20 minutes** after dropping the solution into the well.



STEP 15

Check Your Results

There are three types of results possible: Positive Result, Negative Result and Invalid Result

- a. **Positive result:** if both the quality control line C and the detection line T appear, novel coronavirus antigen has been detected and the result is positive for antigen.
- b. **Negative result:** if there is only a quality control line C and the detection line is colorless, indicating that the novel coronavirus antigen has not been detected and the result is negative.
- b. **Invalid result:** if the quality control line C is not observed, the test is invalid regardless of whether or not there is detection line T (as shown in the figure). Repeat the test with a new unused test card and new nasal sample.



Please notify your Healthcare provider of the results of your Camtech COVID-19 Antigen Rapid Self-Test Kit.

A second test should be done 24 hours to 36 hours later if the test is negative.

INTENDED USE

The Camtech COVID-19 Antigen Rapid Self-Test kit is intended for self-testing for the in-vitro qualitative detection of the SARS-CoV-2 antigen in human anterior nares (nasal) specimen. The fast testing procedure, high sensitivity and simple operation makes this rapid self-test kit a preferred method to detect acute cases of SARS-CoV-2 infection. It is recommended that the test be done before the 7th day after the onset of symptoms.

COVID-19 is an acute respiratory infectious disease to which people are generally susceptible. Patients infected by the novel coronavirus, SARS-CoV-2 are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigations, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations of the disease include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The kit should only be used as a supplementary indicator or used in conjunction with nucleic acid detection in the diagnosis of suspected COVID-19 cases.

TEST PRINCIPLE

This self-test kit uses immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the specimen contains a novel coronavirus, SARS-CoV-2 antigen, the antigen will bind to the colloidal gold-labeled SARS-CoV-2 monoclonal antibody while migrating toward the end of the test membrane. The immune complex will be membrane bound by the monoclonal anti-SARS-CoV-2 capture antibody and display a dark red color at the test line (T) if the specimen is positive for the coronavirus antigen; if the specimen does not contain SARS-CoV-2 antigen, no color will appear. The test card also contains a quality control line (C), which will appear dark red regardless of whether the test line is positive or negative.

STORAGE CONDITIONS & PERIOD OF VALIDITY

1. The kit should be stored between 10°C to 25°C, out of direct sunlight.
2. Shelf-life: 18 months.
3. After the test pouch is opened, the test card should be used within one hour.

LIMITATIONS OF THE SELF-TEST KIT

1. This kit is only used for in-vitro diagnosis in a home use setting.
2. This kit is only used for detecting extracts from human nasal swab samples. The results from other sample types are not suitable.
3. This product is only used for qualitative detection and cannot indicate the level of SARS-CoV-2 antigen in the specimen.
4. This kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination according to doctor's instructions.

PRECAUTIONS

1. Read the instructions carefully before using the kit, and carefully measure the reaction time.
2. The collected samples may be contagious, and the processing and testing operations of the samples should be performed in compliance with local relevant biosafety regulations.
3. Guard against moisture, do not open the test pouch before it is ready for testing. Do not use the test pouch if it is damaged or the test card is damp.
4. Please use the kit within the validity period.
5. Bring all reagents and specimens to room temperature (15 - 30°C) before use.
6. Do not replace the components in this kit with components in other kits.
7. Do not dilute the specimen for testing, otherwise you may get inaccurate results.
8. The kit must be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
9. The test methods and results must be interpreted in strict accordance with this instruction manual.
10. Negative results will occur with this kit if the novel coronavirus antigen titer in the specimen falls below the minimum detection limit for this kit.