

Oral Fluid Test for COVID-19 Antibody

Quick Reference Guide

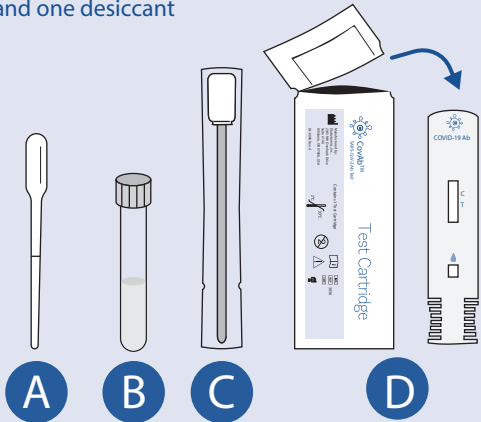
(Read complete instructions for use)

- For Emergency Use Authorization (EUA) only
- For prescription use only
- For in vitro diagnostic use only

1 Patient should not eat or drink 30 minutes prior to testing. Open the kit and identify the components.

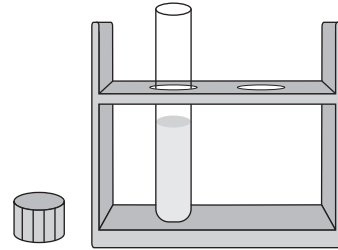
Each box of fifty (50) tests contains 50 Single Test Kits. Each Single CovAb™ SARS-CoV-2 Ab Test Kit contains:

- A. One (1) transfer pipette
- B. One (1) capped tube with sample solution
- C. One (1) packaged oral swab
- D. One (1) foil package with one Test Cartridge and one desiccant

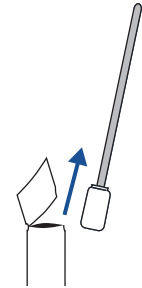


Required but not provided: Timer, Tube rack

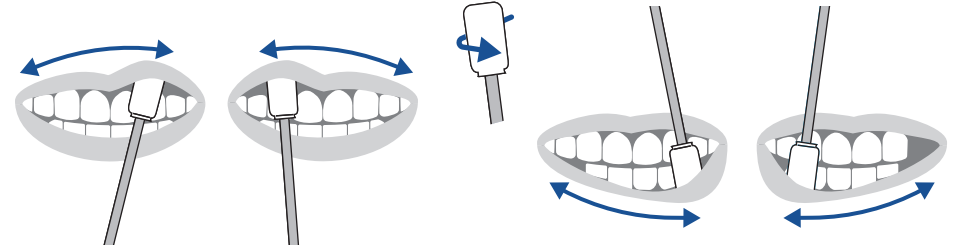
2 Open the sample collection tube and place it in a tube rack.



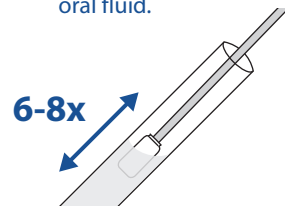
3 Remove the oral swab from its packaging.



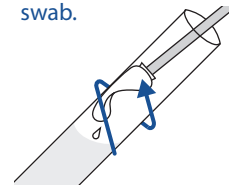
4 Place the swab head against the upper gum line. Apply moderate pressure and slowly wipe the swab across the gum line from right to left all the way to the back of the mouth and then repeat left to right. Flip the swab and repeat the process on the lower gum. Do not brush.



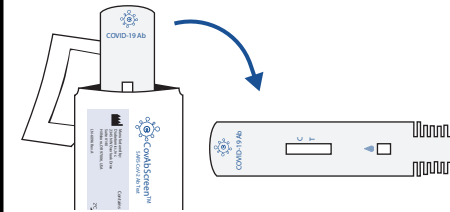
5 Carefully, without splashing, insert the swab into the liquid in the tube and gently push the swab up and down 6-8 times to release and mix the oral fluid.



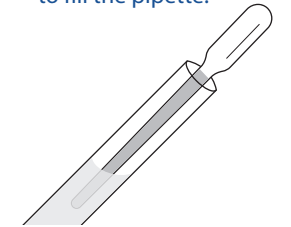
6 Squeeze as much liquid from the swab as possible by pressing each side of the swab 2-3 times against the inside of the tube above the level of liquid. Remove and discard the swab.



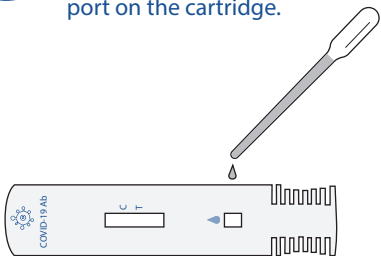
7 Remove the Test Cartridge from its packaging and place it on a level surface. Dispose of the desiccant. Do not use expired Test Cartridge.



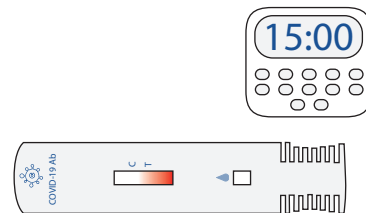
8 Use the transfer pipette to collect the liquid sample until the line marking. Press the bulb completely and release to fill the pipette.



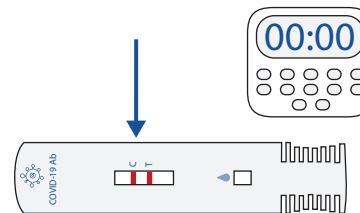
9 Slowly press the bulb of the pipette to transfer 5 drops of the liquid sample to the sample port on the cartridge.



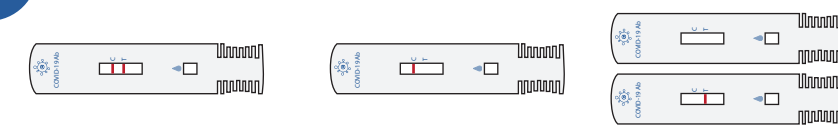
10 Start a timer for 15 minutes and allow the test to run.



11 At 15 minutes, evaluate the lines in the reading window on the Test Cartridge. Do not read after 20 minutes.



12 Interpretation of Test Results



If there are two lines, both C and T (even faint lines), the test is positive for antibodies to COVID-19

If there is only a C line, the test is negative for antibodies to COVID-19

If there is no C line, the test is invalid and the test should be repeated with a new kit.

Dispose of the kit and materials in biohazard waster container.

See opposite side for CovAb™ Controls kit Quick Reference Guide



CovAb™ Control Kit

SARS-CoV-2 Ab Test

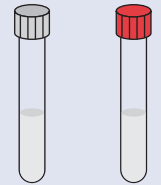
Oral Fluid Test for COVID-19 Antibody

Quick Reference Guide

(Read complete instructions for use)

- For Emergency Use Authorization (EUA) only
- For prescription use only
- For in vitro diagnostic use only

1 Each CovAb™ Control Kit contains:
A. One (1) negative control (clear cap)
B. One (1) positive control (red cap)



A **B**

Required but not provided:
Timer, Tube rack

Controls should be run in the following scenarios:

- A new operator uses the kit
- A new lot of test kits is used
- A new shipment of kits is used
- The temperature used during storage of the kit falls outside of 2-30°C
- The temperature of the test area falls outside of 15-30°C
- To verify a higher than expected frequency of positive or negative results
- To investigate the cause of repeated invalid results

2 The Control Kit will require the use of one test cartridge for testing the negative control and another test cartridge for the positive control.

3 Remove negative control tube from the package and mix by gentle inversion. Do not shake. Do not mix mechanically. Do not dilute the controls. Use as is.

4 Remove the Test Cartridge from its packaging and place it on a level surface. Dispose of the desiccant. Do not use expired Test Cartridge.

5 Open the negative control tube and place it in a tube rack.

6 Use the transfer pipette to collect the liquid sample until the line marking. Press the bulb completely and release to fill the pipette.

7 Slowly press the bulb of the pipette to transfer 5 drops of the liquid sample to the sample port on the cartridge.

8 Start a timer for 15 minutes and allow the test to run.

9 At 15 minutes, evaluate the lines in the reading window on the Test Cartridge. Do not read after 20 minutes. Negative control will display as shown below.

10 Repeat steps 4-8 with positive control. At 15 minutes, evaluate the lines in the reading window on the Test Cartridge. Do not read after 20 minutes. Positive control will display as shown below.

11 Interpretation of Control Results

Positive control should show both C and T lines. Negative control should show only C line.

If the controls do not provide expected results, stop testing and contact customer support.

Dispose of the kit and materials in biohazard waster container.