



# CovAb™ Control Kit

SARS-CoV-2 Ab Test

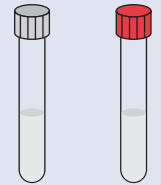
# Oral Fluid Test for COVID-19 Antibody

## 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.

Manufactured by:  
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LN-6105, Rev. E

This product has not been FDAcleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for detecting the presence of total antibodies to SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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