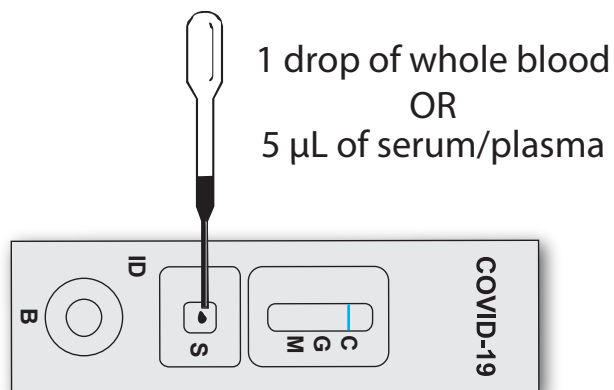


# SARS-CoV-2 ANTIBODIES TEST USAGE INSTRUCTIONS

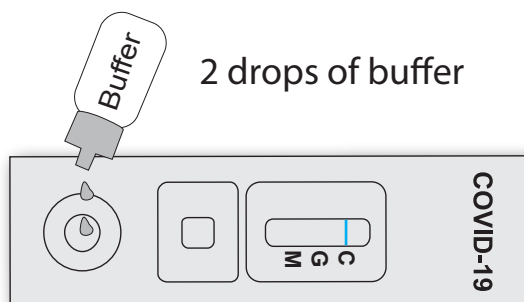
## STEP 1: Add Specimen

Remove the test cassette from the sealed foil pouch and use it as soon as possible. Lay device on flat surface and add the specimen.



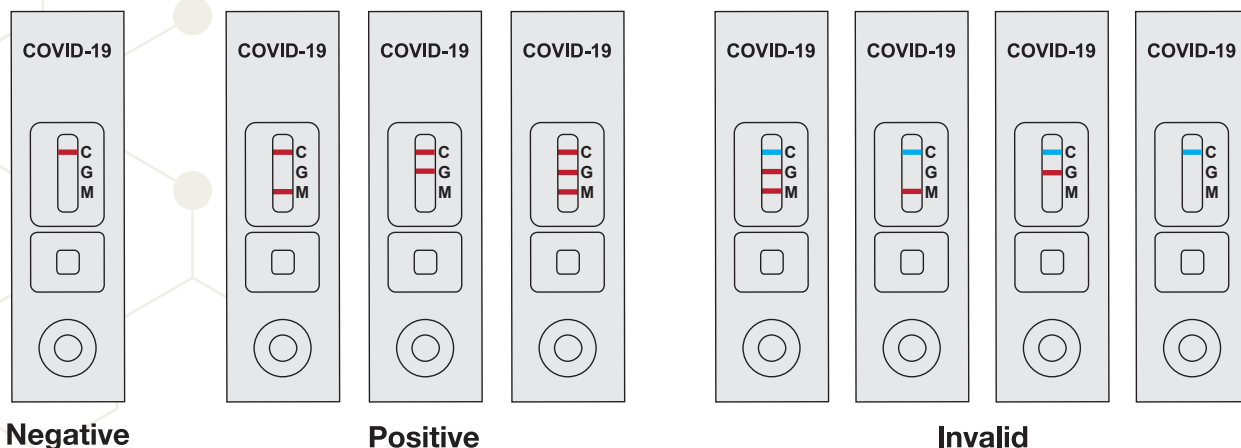
## STEP 2: Add Buffer

Immediately add 2 drops (about 80 µL) of sample buffer to the buffer well (B) ensuring that buffer vial tip does not touch the sample. Avoid air bubbles.



## STEP 3: Read Results

Read results in 10 min. Do not interpret after 15 min.



## SARS-CoV-2 ANTIBODIES TEST INTERPRETATION GUIDE

TEST RESULTS		RECOMMENDATIONS
IgM	IgG	
Negative	Negative	SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. <i>No Symptoms:</i> Patient not suspected of having SARS-CoV-2 (see the important warnings at the bottom of the page) <i>With Symptoms:</i> Patient could have been recently infected and the body hasn't produced antibodies yet. Proceed immediately to a molecular (RT-PCR) test and further examination.
Positive	Positive	Patient is infected and must be isolated. Further examination and testing is required.
Positive	Negative	Patient is infected and must be isolated. Further examination and testing is required.
Negative	Positive	Patient may have been infected previously, but recovered. Further examination and testing is required.

This test can be sold under the FDA's Emergency Use Authorization (EUA) program.

### WARNINGS:

- This test has not been approved by FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in recent contact with the virus. Follow-up testing with a molecular diagnostic test (RT-PCR) should be considered in order to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform of infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- This test is for use by licensed laboratories and does not apply to at-home testing.