

# AssureTech Ecotest COVID-19 IgG/IgM Rapid Test Device



CLIA  
waived\*

**The AssureTech Ecotest COVID-19 IgG/IgM test is a serology tool to help assess patients who may have been previously infected with SARS-CoV-2.** As a supplement to molecular testing, this test can alleviate the strain on your lab's molecular test load.

Antibody testing can identify previously infected patients by detecting the body's immune response to the virus. Results from these tests can help identify who has been infected and developed antibodies that may protect from future infection as well as identify those still at risk.

Antibody testing, in addition to other information such as confirmatory diagnostic tests, medical history, and symptoms, may also help health care professionals make more informed decisions regarding how to best take care of their patients.

## Key features

- Sensitivity: 100%
- Specificity: 98.8%
- Overall 99.4% accuracy
- Authorized for use with fingerstick and venous whole blood, serum, and plasma specimens
- CLIA Waived\*
- For Emergency Use Authorization Only
- 15 minutes to results

## Key facts to keep in mind

- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform waived, moderate or high complex testing.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform 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.

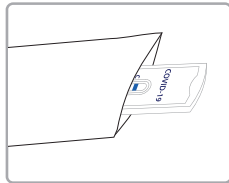
\*Only waived for fingerstick whole blood specimens

# How to use

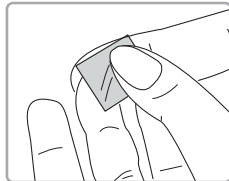
There should be a blue line in the control region before testing (next to “C”), discard the device if there is not a blue line.

## For fingerstick whole blood specimens

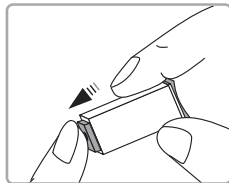
1. Bring pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it as soon as possible.



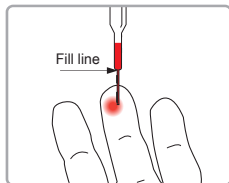
2. Clean the puncture site with the alcohol prep pad provided.



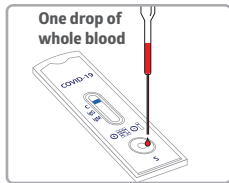
3. Remove the cap. Push the safety lancet firmly against the puncture site.



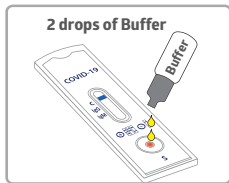
4. Draw the specimen above the fill line.



5. Transfer one drop of specimen into the specimen well. **Adding more or less than 1 drop of specimen may lead to erroneous results.**

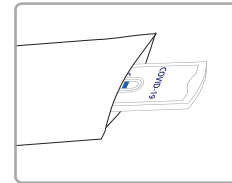


6. Add 2 drops of buffer and start the timer. **Adding 1 drop of buffer or more than 4 drops of buffer may lead to erroneous results.** Wait for the blue line to change to a red line.

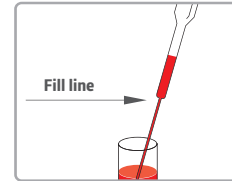


## For venous whole blood specimens

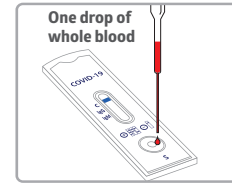
1. Bring pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it as soon as possible.



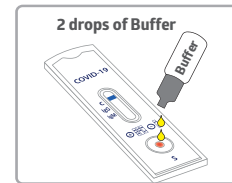
2. Using the provided disposable pipette, draw the specimen above the fill line (avoid the specimen entering the bubble of disposable pipette).



3. Transfer 1 drop of the specimen into the specimen well of the test device.



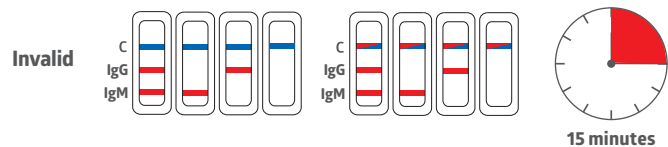
4. Then add 2 drops of buffer and start the timer. Wait for the blue line to change to red.



For serum or plasma specimens, please see product IFU.

## How to read results

Read result at 15 minutes after adding buffer, do not interpret the result after 30 minutes, and do not read results earlier than 15 minutes. There should be a blue line in the control region before testing (next to the “C”), discard the device if there is no blue line.



## Ordering information

Item No.	Description	Pkg.
AZFAZCOVID10P	Ecotest COVID-19 IgG/IgM Rapid Test Device	20/bx
AZFCOV19CTRL	Ecotest COVID-19 IgG/IgM Rapid Test Control	1PK

Contact your Medline Representative or call 1-800-MEDLINE to discuss purchasing options and supply availability.

This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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