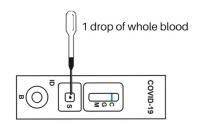
SEQUENCE46



## COVID-19 IgG/IgM Rapid Test Instructions

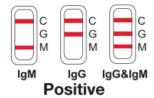
- 1. Remove the test cassette from the sealed pouch and lay the device on a flat surface.
- 2. Using an alcohol swab, clean off the fingertip to be used for finger prick.
- 3. Lance the patient's fingertip with a lancet of your choice.
- 4. Transfer one (1) large, hanging drop of whole blood ( $^{\sim}10\mu$ L) to the sample well (S) of the test device. If drop is not plentiful, use the small transfer pipette from the kit to transfer the drop of blood; volume should reach just beyond the narrow part of the pipette.



- 5. Immediately add two (2) drops ( $^{80}\mu$ L) of buffer to the buffer well (B) of the test device. Avoid air bubbles. DO NOT ALLOW BUFFER VIAL TIP TO TOUCH THE SPECIMEN OR DEVICE.
- 6. Wait for the control (C) line to change from blue to red.
  - a. If after two (2) minutes the sample has not moved across the test window OR if blood is still present in the sample well (S), add one (1) additional drop of buffer to the buffer well (B).
- 7. Results should be read after 10 minutes. Do not interpret the results after 15 minutes.

## Interpretation:

IgM antibodies appear in blood as soon as 3-5 days after infection for symptomatic patients and 7 days after infection for asymptomatic patients. IgG antibodies appear in blood within 2 weeks after infection. Over time, blood concentrations of both IgM and IgG decrease - IgM becomes undetectable but IgG will remain elevated.







Invalid

## WARNING

This test has been validated but independent review by the FDA is not yet complete. Emergency Use Authorization (EUA) has been submitted and is pending.

This product is intended for professional use and not for home use. Results from antibody testing are presumptive and <u>should not be used as the sole basis</u> to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

A negative result may appear and not correlate with symptoms. A medical professional is required to consider various factors, including confirmation testing, when receiving a presumptive result.

**NOTE:** Kits can be stored at room temperature or refrigerated - DO NOT FREEZE. Do not use kits after expiration date.