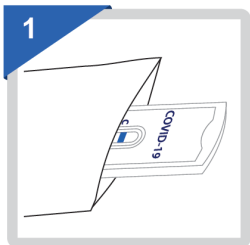# Quick Reference Instructions
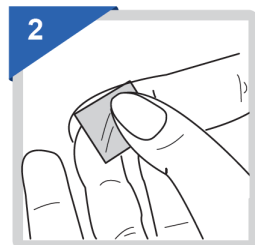# Assure COVID-19 IgG/IgM Rapid Test Device

1 This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. It is a point-of-care test for finger-stick whole blood specimens only. The user should be trained in the procedure. Wear appropriate protective attire for your safety when handling patient samples.

2 This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

3 Read the complete Quick Reference Instructions before performing the test. For assistances, please call 1-888-686-9909.

4 There should be a blue line in the control region (next to "C") before testing, discard the device if there is no blue line.

5 Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

Before you begin, refer to the Package Insert, read through this entire Quick Reference Guide, and bring the test components shown below to room temperature PRIOR to running the test.
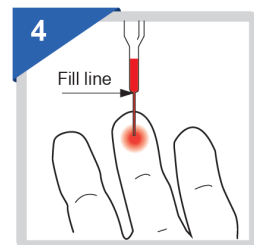

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
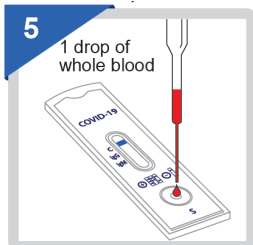
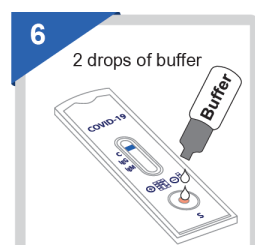**2.** Clean the puncture site with the alcohol prep pad provided.

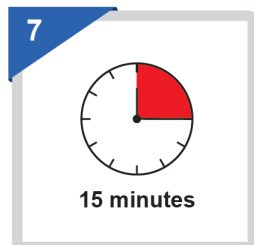**3.** Remove the cap and push the safety lancet firmly against the puncture site.

4. Draw the specimen above the fill line.

Fill line

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

1 drop of whole blood

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

2 drops of buffer

7. Read the result after 15 minutes. Do **NOT** interpret the result after 30 minutes.

15 minutes

IgG & IgM Positive

IgG Positive

IgM Positive

Negative

Invalid

Invalid