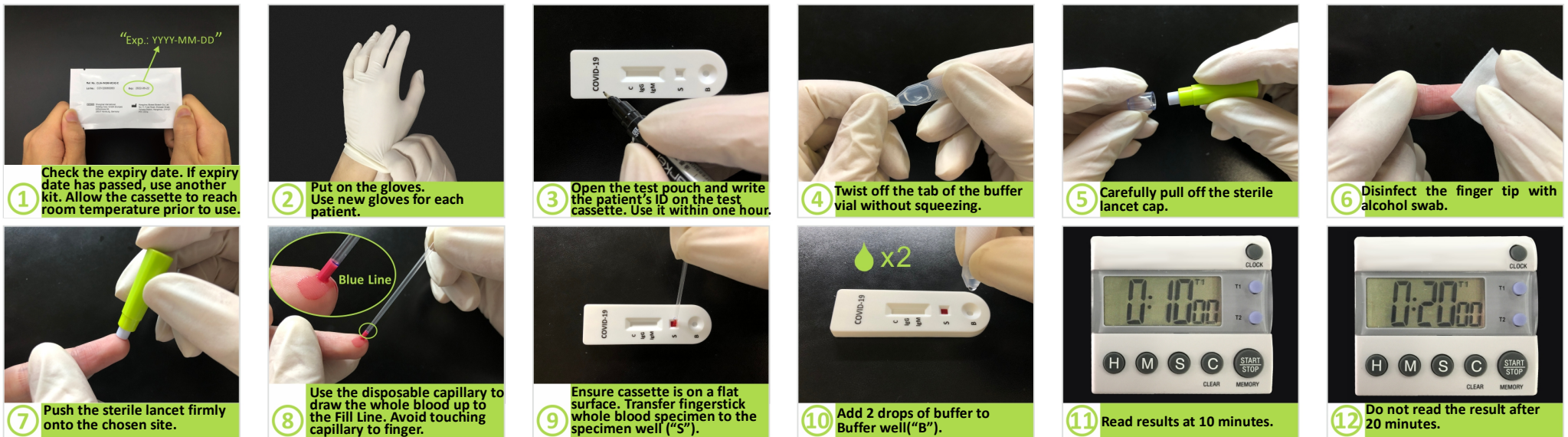
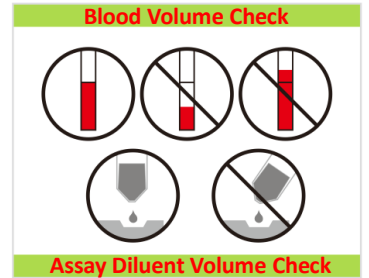


Test Procedure

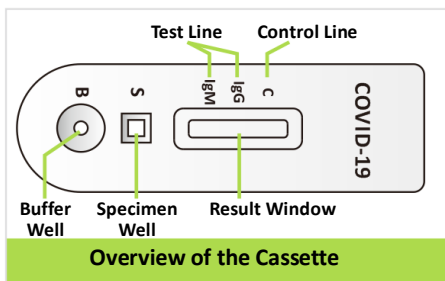
Note:

1. This test has not been cleared or approved, but has been authorized for use with fingerstick whole blood specimens by laboratories certified under CLIA that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
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. The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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 declaration is terminated or authorization is revoked sooner.
3. The user should be trained in the procedure. Wear appropriate protective attire for your safety when handling patient samples.
4. Read the complete Quick Reference Instructions before performing the test. For technical assistance, please call +1(888) 882 7739, or +1(858) 481 5031.
5. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.



All used tests, specimens and potentially contaminated materials should be discarded according to local regulations.

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Positive			Invalid	
			Control line fails to appear. Review the procedure and repeat the test with a new test cassette.	
Negative				

CLIAwaived™ Inc.

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CORONACHEK™ CoronaCHEK SARS-CoV-2 IgG/IgM External Control Kit Quick Reference Guide

