RightSign™ COVID-19 IgG/IgM Rapid Test Cassette (Format 2)

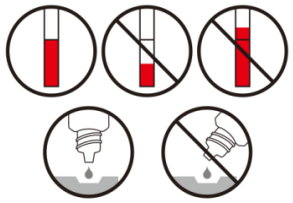
Quick Reference Guide

Test Procedure

Preparation

Test pouch (Test Device) | Buffer | Sterile lancet | Disposable capillary | Alcohol swab | Disposable Gloves (Not Provided) | Timer (Not Provided)

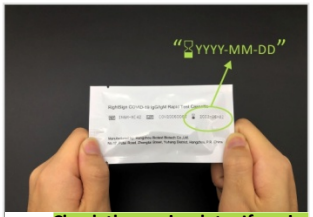
Blood Volume Check



Assay Diluent Volume Check

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 (858) 866 8382.
5. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

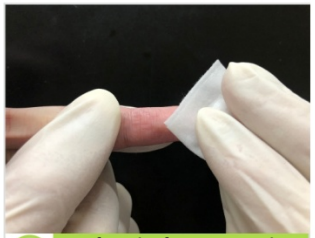


1 Check the expiry date. If expiry date has passed, use another kit. Allow the cassette to reach room temperature prior to use.

2 Put on the gloves. Use new gloves for each patient.

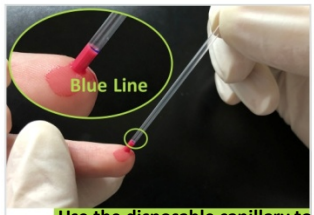
3 Open the test pouch and write the patient's ID on the test cassette.

4 Carefully pull off the sterile lancet cap.



5 Disinfect the finger tip with alcohol swab.

6 Push the sterile lancet firmly onto the chosen site.



7 Use the disposable capillary to draw the whole blood up to the Fill Line. Avoid touching capillary to finger.

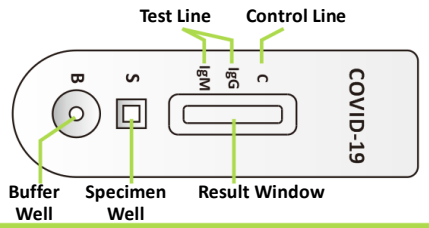
8 Ensure cassette is on a flat surface. Transfer fingerstick whole blood specimen to the specimen well ("S").

9 Add 2 drops of buffer to Buffer well("B").

10 Read results at 10 minutes.

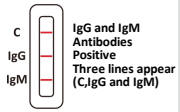
11 Do not read the result after 20 minutes.

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

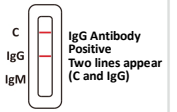


Overview of the Cassette

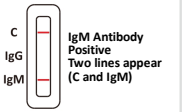
Positive



IgG and IgM Antibodies Positive
Three lines appear (C,IgG and IgM)

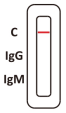


IgG Antibody Positive
Two lines appear (C and IgG)



IgM Antibody Positive
Two lines appear (C and IgM)

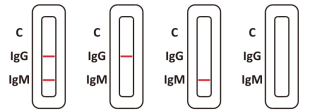
Negative



Only one colored line appears in the control region (C).

Invalid

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



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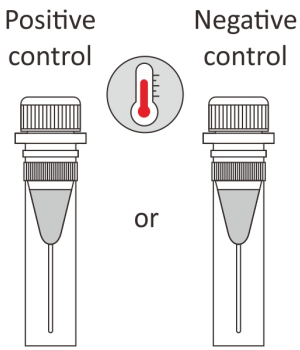
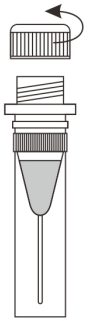
Made in China

RightSign™ SARS-CoV-2 IgG/IgM External Control Kit

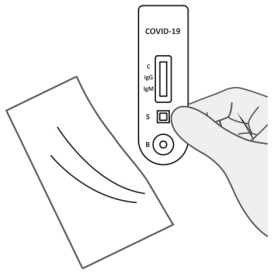
Quick Reference Guide



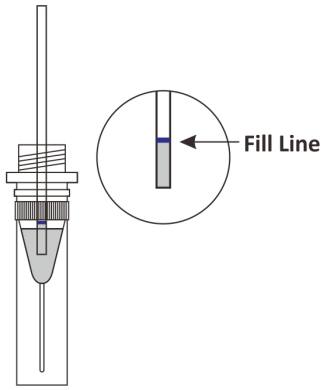
1 Allow the controls to reach room temperature prior to use. Mix gently before use.



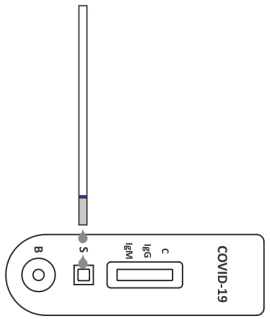
2 Unscrew the cap of positive control or negative control.



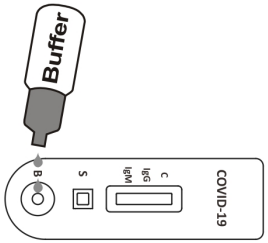
3 Remove the test cassette and place it on a clean and level surface. Use it within one hour.



4 Use the disposable capillary to draw negative or positive control up to the Fill Line.



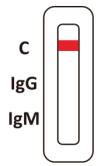
5 Add 10 ul of negative or positive control into specimen well (”S”).



6 Transfer 2 drops (approximately 80ul) of buffer to the buffer well (”B”).

7 Read results at 10 minutes. Do not interpret results after 20 minutes.

For positive control



For negative control