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

PLYMOUTH MEDICAL

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 fingerstick 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 technical assistances, please call 888-392-5076.
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.

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1.Remove the test cassette from the sealed pouch and use it as soon as possible.

Before you begin

-Refer to the package insert for more information

-Read through the entire Quick Reference Instructions before beginning a test

-Bring test components show below to room temperature before starting

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

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

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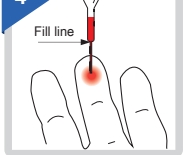
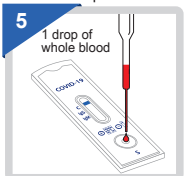


4.Draw the specimen above the fill line.

5



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

6

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 change to red line.

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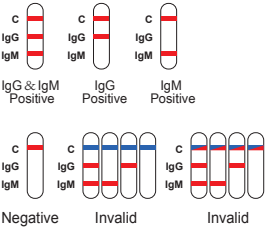
7. Read result at 15 minutes after adding buffer, do not interpret the result after 30 minutes.



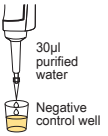
Quick Reference Instructions of COVID-19 IgG/IgM Control

(not included with test package, can be purchased separately)

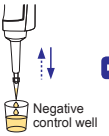
For Positive control

1. Remove the control well from the sealed pouch and use it as soon as possible.

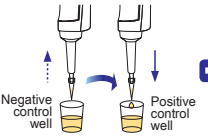
2. Open the positive control and one of the negative control.



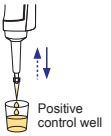
3. Add 30µl purified water into the negative control well by micropipette.



4. Draw the liquid up and down for 5-10 times to vigorously mix.



5. Transfer all the mixed liquid of negative control into the positive control well.

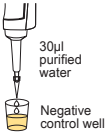


6. Draw the liquid up and down for 5-10 times to vigorously mix and wait to be used.

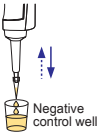
For Negative control

1. Remove the negative control well from the sealed pouch and use it as soonas possible.

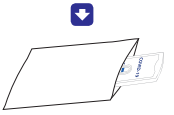
2. Open one of the negative control.



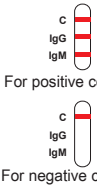
3. Add 30µl purified water into the negative control well by micropipette.



4. Draw the liquid up and down for 5-10 times to vigorously mix and wait to be used.



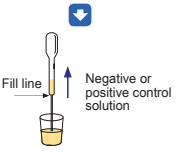
- Remove the test cassette from the sealed pouch and use it as soon as possible.



- Read result at 15 minutes after adding buffer, do not interpret the result after 30 minutes.

- Add 2 drops of buffer and start the timer. Wait for the blue line change to red line.

- Transfer 1 drop of positive or negative control solution into the specimen well.



- Draw the positive or negative control solution above the fill line.

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