



Megna Health Inc.

User Quick Reference Instructions for Rapid COVID-19 IgM/IgG Combo Test Kit

Fingerstick Whole Blood

Ver 1.02 4-21-2021

For use under Emergency Use Authorization Only
For Prescription Use only
For In Vitro Diagnostic Use Only

- This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This test has been authorized only for detecting the presence of IgM and IgG antibodies to 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 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 declaration is terminated, or authorization is revoked sooner.

READ ALL OF THESE INSTRUCTION BEFORE DOING THE TEST.

This test involves taking a drop of blood sample from fingertip using a single use lancet. When doing the test, pay particular attention to the instructions on how to draw the sample.

WHAT COMES IN YOUR KIT?



Rapid COVID-19 Test Card
(when removed from pouch)



Auto single-use lancet



5 µL Capillary straw for sample collection



Sample Buffer (single use)

TEST PROCEDURES

1. Tear open the pouch to take out the test card. Place the Rapid COVID-19 Test Card on a table or other flat surface. Check that kit has not expired. Bring kit components to room temperature.



2. Clean the fingertip where blood sample will be taken using clean water or alcohol wipe.



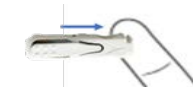
3. Twist cap of the lancet 360 degrees to remove the cap. Apply the lancet to fingertip of the middle or ring finger, then press the trigger.



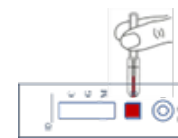
4. Collect blood sample using the 5 µL capillary straw.

Caution: Filling is automatic. Never squeeze before or while sampling.

Hold the 5 µL capillary straw horizontally and touch the tip of the straw to the blood drop on fingertip. Capillary action will automatically draw the sample to the fill mark, then stop.



5. Add one drop (5µL) of blood sample to the “S” area of the Rapid COVID-19 Test card. To expel the sample, align the tip of the 5 µL capillary straw with the sample well. Squeeze the bulb of the capillary straw.



6. Add sample buffer. Tear open the sample buffer ampule, add 2 drops to the “Buffer” well on the test card.

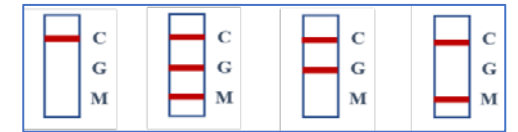


7. Wait for 15 minutes.

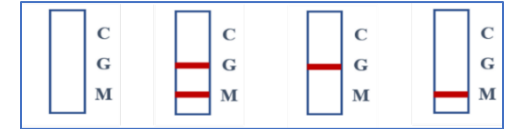


8. Read the result. Determine if the test is negative or positive by comparing to possible results shown below. Do not read the result after 15 minutes. Note: Results recorded after 20 minutes may not be accurate.

POTENTIAL TEST RESULTS



Negative Positive IgM & IgG Positive IgG Positive IgM



Results not valid, repeat the test.

EXTERNAL CONTROL TEST

Users should refer to the instructions for use for the external controls. External controls should be run like human specimens using the instructions described herein. It is recommended that positive and negative controls are tested each time a new lot is used, when a new operator performs the test, or when the test is run in a new room etc. to confirm the test procedure and to verify proper test performance.

External Control Test Procedures

1. Thaw the control material at room temperature until they are completely thawed prior to use.
2. Add one drop or 5 µL of control sample to “S” well on the test card. Test positive or negative controls separately.
3. Tear open the buffer ampule, add 2 drops to the “Buffer” well on the test card.
4. Read the results at 15 minutes.

Expected External Control Results

POSITIVE CONTROL	NEGATIVE CONTROL

- Positive controls: Positive bands in both IgM and IgG.
- Negative controls: Negative in both IgM and IgG
- If controls do not provide the expected results, repeat the test with a new Rapid COVID-19 Test Card and controls; If the results are still not correct, contact Megna Health at support@megnahealth.com.

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