IVD

AllCheck COVID-19 IgG/IgM

※ **Please read the instructions for use carefully.**

[INTENDED USE]

All*Check* COVID-19 IgG/IgM is a rapid immunochromatographic test for the qualitative detection of IgM and IgG antibodies to the SARS-CoV-2 in human serum, plasma, venous or capillary whole blood. Results from the **All*Check* COVID-19 IgG/IgM** System should not be used as the sole basis for diagnosis.

[SUMMARY]

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by SARS-CoV-2, a new strain of coronavirus that has not been previously identified in humans. The disease is primarily spread between people via respiratory droplets from infected individuals when they cough or sneeze. Time from exposure to onset of symptoms is generally between 2 and 14days. The disease may initially present with few or no symptoms, or may develop into fever, coughing, shortness of breath, pain in the muscles and tiredness.

Detection of SARS-CoV-2 IgM and IgG antibodies in human blood can be used as an auxiliary means for early screening of COVID-19. SARS-CoV-2 IgM antibody could be detected in patient blood in 3-5 days after onset and IgG could be detected in 7 days after onset. However, the trend of IgM and IgG changes in different cases is not exactly the same. As it is a novel disease diagnosis and treatment of which are being *explored, please refer to the latest guidelines for diagnosis and treatment of COVID-19.*

[TEST PRINCIPLE]

All*Check* COVID-19 IgG/IgM is designed for qualitative determination of IgM and IgG antibodies to the SARS-CoV-2 in human serum, plasma and whole blood. The test uses mixed recombinant SARS-CoV-2 nucleocapsid protein (N protein) and spike protein (S protein) both conjugated with colloidal gold and anti-human IgM and IgG antibody coated on different test lines respectively. After the samples has been applied to the test strip, the gold-labelled recombinant SARS-CoV-2 N protein and S protein will bind with SARS-CoV-2 IgM or IgG antibody in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by anti-human IgM and IgG antibody resulting in purplish red streaks on the test lines. The color intensity of each test line increases in proportion to the amount of SARS-CoV-2 IgM and IgG antibody in sample.

[REAGENTS AND MATERIALS]

1. COVID-19 Test devices
2. Dropping Bottle containing sample diluent
3. 10 ㎕ Capillary pipette
4. Instructions for use

Materials not provided but required: Lancet, Alcohol wipes, Gloves, Timer.

[STORAGE AND STABILITY]

Store at 1~30℃(34~86˚F) for 12months from the date of manufacture. Keep the test cassette in sealed pouch until use. Do not open pouch until you are ready to perform a test. Do not use the test beyond the indicated expiration date.

[WARNINGS AND PRECAUTIONS]

1. For In Vitro Diagnostic Use only. Do not re-use test device.
2. Do not use the device past its expiration date.
3. To obtain accurate results, you must follow the package insert instruction.
4. Store the devices at 1~30℃(34~86˚F). Do not freeze.
5. Before testing, leave at room temperature if you store at refrigerator.
6. Do not use the test kit if the packing is damaged or the seal is broken.
7. Use the devices immediately after opening the aluminum pouch
8. Do not touch the zone of membrane.
9. Do not mix the components from different lot to lot.
10. Do not eat or smoke while handling specimens.
11. Wear protective gloves and mask while handling specimens. Wash hands thoroughly afterwards.
12. Avoid splashing or aerosol formation.
13. Clean up spills thoroughly using an appropriate disinfectant.
14. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
15. All waste except liquid should be autoclaved at 121℃ for more than 1 hour or decontaminated and disposed in accordance with local and international regulations.
16. Please calibrate the pipette when you transfer the samples.
17. Use separately disposable capillary tube or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

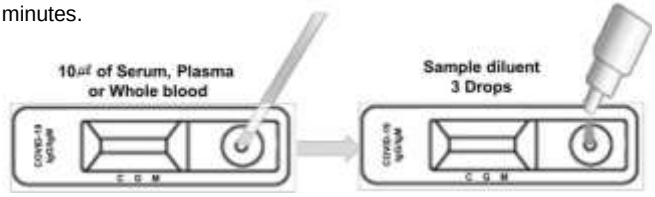
[SPECIMEN COLLECTION AND PREPARATION]

1. Sample should be human serum, plasma, fingertip blood and venous whole blood. Other body fluid and samples may cause incorrect or inaccurate results.
2. [Fingertip blood or whole blood specimen]
Fingertip blood should be used immediately after collection.
Collect an anti-coagulated blood sample (heparin, citrate and EDTA).
Whole blood samples must be tested within 24 hours after collecting.
3. [Plasma/Serum specimen]
Centrifuge whole blood to get plasma or serum specimen. Testing should be performed immediately after the specimen shave been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

[TEST PROCEDURE]

All specimens and test devices should be same temperature with environment of experiments. Leave it for 15~30 minutes at room temperature (15~25℃) before using.

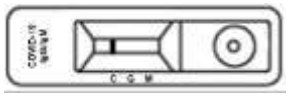
1. Remove the test device from the aluminum pouch and place the device on a flat horizontal surface.
2. Transfer 10 ㎕ of serum, plasma or whole blood using capillary tube or pipette into the sample well(S) and then add 3 drops(about 100 ㎕) of sample diluents.
3. Read the result at 10minutes. Do not interpret test result after 15 minutes.



[RESULT INTERPRETATION]

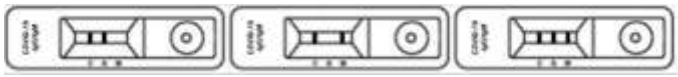
1. Negative Result

The presence of red line in the control region and the complete absence of a line in the test region of the result window



2. Positive result

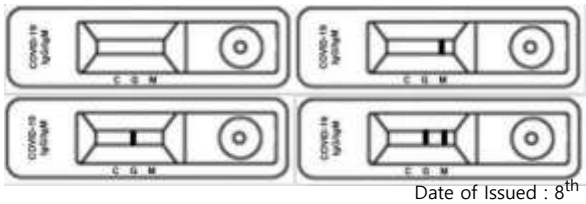
The presence of red line in the test region and in the control region of the result window.



IgG Positive | IgM Positive | IgG, IgM Positive

3. Invalid result

The complete absence of a line in the control region of the result window, regardless of the test line, indicates the device has failed to perform correctly. Re-test is recommended.



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[CLINICAL EVALUATION]

1. For the Clinical sensitivity, 31 positive serum samples were collected from individuals who tested positive with a RT- PCR method for SARS-CoV-2 infection and were collected within 8-40 days after onset of symptoms. 29 of 31 were found be reactive with All*Check* COVID-19 IgG/IgM. Sensitivity(%) is 93.5%
2. For the Clinical specificity, 40 negative serum samples were collected from individuals who tested negative with a RT-PCR method for SARS-CoV-2 infection, 37 were found to be non-reactive with All*Check* COVID-19 IgG/IgM.

Specificity	All*Check* COVID-19 IgG/IgM	
	IgM	IgG
samples	95.0% (38/40)	97.5% (39/40)
Total	92.5%(37/40)	

[LIMITATIONS]

1. A negative result does not preclude the possibility of infection with COVID-19. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. If symptoms persist and the result from the All*Check* COVID-19 IgG/IgM is negative or nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.

SYMBOLS USED ON THE PACKAGE			
IVD	For in Vitro Diagnostics Use		Caution
	Do not reuse		Temperature limitation "Store at 1-30℃"
	Consult instructions for use		Used by
LOT	Lot Number	REF	Part number
Σ	Sufficient for		Manufacturer

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