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COVID-19 IgM/IgG Rapid Test Cassette

IgM Results			IgG Results		
100%	98%	98%	97%	98%	97%
Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy

USA Manufacturer

COVID-19 Specific

Simple Sample Collection

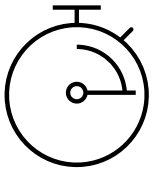
Large Clinical Evaluation

EUA

FDA Emergency Use Authorization

Used Globally

Easily Deployed At Scale



Immediate Results

No Swabbing

For more information please email Info@PGMConsultants.com

RESULTS FROM A RAPID ANTIBODY TEST SHOULD NOT BE USED AS THE SOLE BASIS FOR A DEFINITIVE POSITIVE OR NEGATIVE DIAGNOSIS. ALWAYS SEEK MEDICAL ADVICE IF YOU EXPERIENCE SYMPTOMS OF COVID-19

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Brought to you by Precision Global Medical Solutions, LLC, the exclusive US Distributor for MEDFLOW Clinical COVID-19 IgG/Igm Rapid Test Cassette

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COVID-19 IgM/IgG Rapid Test Cassette

(Whole Blood/Serum/Plasma)

IgM Results

100% Sensitivity

98% Specificity

98% Accuracy

IgG Results

97% Sensitivity

98% Specificity

97% Accuracy

Simple Rapid Effective

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Understanding IgM and IgG

IgM and IgG are types of immunoglobulins, they are commonly called antibodies. When a person becomes infected with a pathogen such as COVID-19, immunoglobulins are produced as a response. The immunoglobulins bind to specific binding sites (antigens) on the surface of the pathogen, this flags the pathogen as foreign matter. This triggers a secondary immune response which in turn attacks and clears the pathogen.

IgM (immunoglobulin M) is the largest immunoglobulin in humans and it is the first antibody to be produced when a person becomes infected. IgM has multiple antigen binding sites and is commonly thought of as a 'general' antibody since it is able to bind to many different pathogens. For COVID-19 the levels of IgM in the blood are at a detectable level between 3-7 days after the onset of infection.

IgG (immunoglobulin G) is a much smaller immunoglobulin and is produced in response to a specific antigen on the pathogen. Levels of IgG rise later than IgM which would indicate previous exposure to COVID-19. IgG also has a function in long term immunity, but exactly how long IgG remains after the infection is cleared appears to be highly variable, IgG has a half-life of 7-30 days[8], although it may be detected after many half-lives.

In combination, IgM and IgG can be used to detect both early and late stage COVID-19 and also long term immunity after recovery. It is important to understand that the IgG is specific to 2019-nCoV, but using this specific IgG and the general IgM, a simple lateral flow immunoassay diagnostic test for the COVID-19 can be produced.

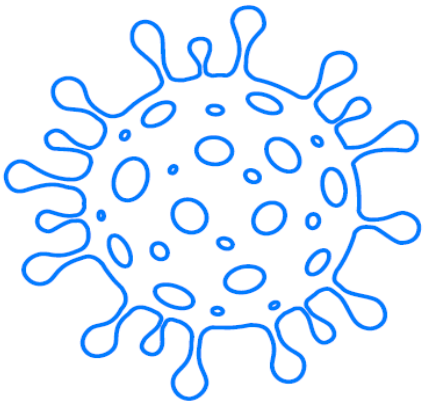
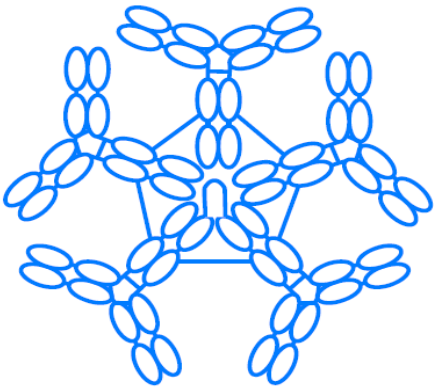
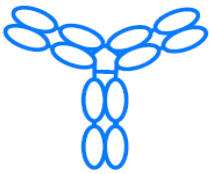


Illustration of Coronavirus



Immunoglobulin M (IgM) Illustration



Immunoglobulin G (IgG) Illustration

8. Mankarious S, Lee M, Fischer S, Pyun KH, Ochs et al. (1988). The half-lives of IgG subclasses and specific antibodies in patients with primary immunodeficiency who are receiving intravenously administered immunoglobulin. J Lab Clin Med 112(5); 634-640

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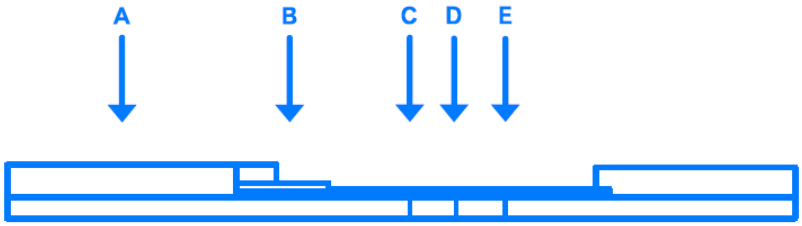
The COVID-19 IgM/IgG Rapid Test Cassette

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in the IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in the IgG test line region. If the specimen contains IgG antibodies to COVID-19, a coloured line will appear in IgG test line region as a result. Similarly, anti-human IgM is coated in the IgM test line region and if specimen contains IgM antibodies to COVID-19; the conjugate-specimen complex reacts with anti-human IgM and a coloured line appears in IgM test line region as a result.

Therefore, if the specimen contains COVID-19 IgG antibodies, a coloured line will appear in IgG test line region. If the specimen contains COVID-19 IgM antibodies, a coloured line will appear in IgM test line region. If the specimen does not contain COVID-19 antibodies, no coloured line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.



As shown in the illustration above, the specimen (A) migrates via capillary action along the membrane to react with the gold conjugate (B). COVID-19 IgG and/or IgM present in the specimen binds to the conjugate, forming a coloured Novel coronavirus antibody-antigen complex. The mouse anti-human IgG and mouse anti-human IgM immobilized in the test zone of the membrane captures the test region (C) and test region (D). The formation of a visible coloured line in the test region indicates a positive result (C) or (D). The absence of a coloured line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture coloured conjugate regardless of test specimen composition. The resulting visible coloured band (E) confirms control line.

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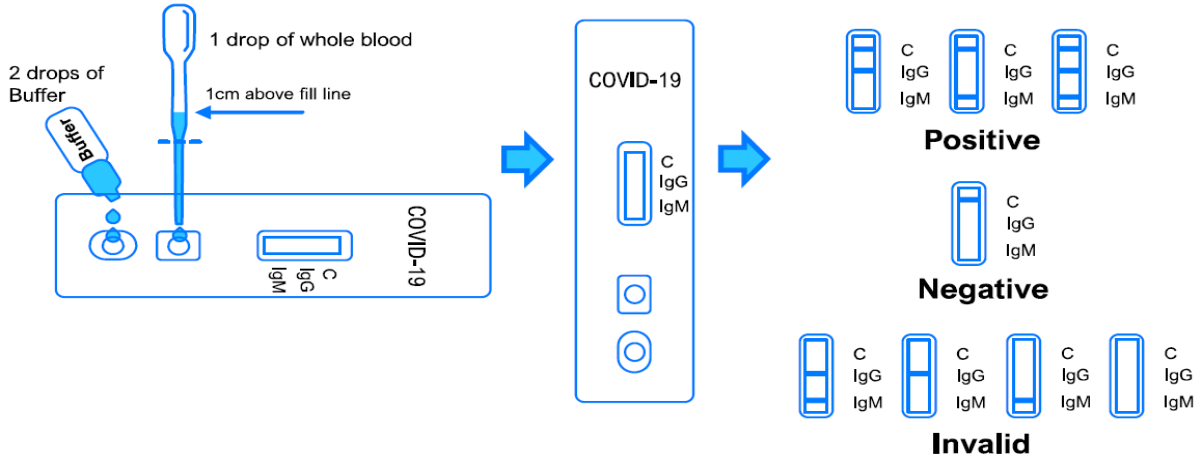
How to Use and Understand

The 2019-nCoV IgM/IgG Rapid Test Cassette



To perform the test, a sample of venous whole blood is placed at the inlet, before the addition of a buffer solution. Any IgG/IgM present in the sample will bind to the gold-COVID-19 antigen conjugate and flow to the two test lines, which will capture any IgG/IgM in the sample. The control line will then capture the other gold-antibody conjugate, confirming the test is valid. In approximately 10 minutes, test lines will appear for both IgG and IgM for a positive result, and a control line for quality control. Only one test line (IgG or IgM) is required for a positive diagnosis. This test has the advantages of being portable, rapid and low cost.

Accuracy of the COVID IgG/IgM Rapid Test Cassette

While the test is highly accurate, it should also be understood that no test is infallible. As stated previously the 'gold-standard' RT-PCR test is also known to give false positive results. To establish the accuracy of the COVID-19 IgG/IgM Rapid Test Cassette there are two important sets of results to consider; Sensitivity and Specificity.

Relative Sensitivity for this test relates to its sensitivity to the antibodies produced by the body in response to a COVID-19 infection, when compared with a sensitivity of a gold-standard RT-PCR Test.

Relative Specificity for this test means its ability to correctly identify the specific antibodies produced in response to a COVID-19 infection, when compared with a sensitivity of a gold-standard RT-PCR Test.

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Frequently Asked Questions

1. **Accuracy of the COVID IgG/IgM Rapid Test Cassette**
   Yes, the COVID-19 IgG/IgM Rapid Test Kit is authorized for CLIA Moderately Complex and Highly Complex labs under the FDAs EUA (Emergency Use Authorization) process.

2. **What does Covid-19 IgG/IgM Rapid Test Cassette detect?**
   The test detects IgG and IgM immunoglobulins (antibodies) to the COVID-19 virus in human whole blood, serum or plasma.

3. **Is the test specific for COVID-19?**
   Yes, the IgG that the test detects is specific to COVID-19, a positive result would indicate COVID-19 infection. The IgM is more general, its detection combined with IgG and/or symptoms of COVID-19 would also indicate infection. This rapid test can be used for primary and secondary diagnosis of COVID-19.

4. **What sample can be used with the test?**
   Yes, there are no issues with testing babies and young children. There is no harm to pregnant or breast feeding women or their babies when performing a test.

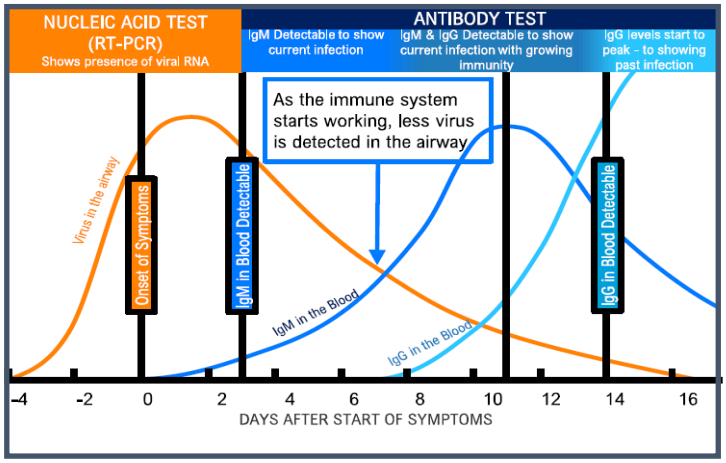
5. **Can babies, young children, pregnant women, or breastfeeding women be tested?**
   Yes, there are no issues with testing babies and young children. There is no harm to pregnant or breast feeding women or their babies when performing a test.

6. **Is there anyone who should not be tested using the COVID-19 IgG/IgM Rapid Test Cassette?**
   No, testing is a vital strategy for helping to control and understand the virus and may result in improved measures to prevent its spread. However, as a blood sample is required anyone with a blood related health condition such as hemophilia or hemochromatosis should discuss this with a healthcare professional before receiving this test.

7. **What is the shelf-life of the COVID-19 IgG/IgM Rapid Test Cassette?**
   The shelf-life is 24 months from date of manufacture. Do not use after the expiry date.

8. **How should the COVID-19 IgG/IgM Rapid Test Cassette be stored?**
   We recommend that the tests are stored between 4-30°C, this does not mean you should refrigerate them as the test should be performed at room temperature (15-30°C). Do not freeze.

9. **When can the COVID-19 IgG/IgM Rapid Test Cassette detect an infection?**
   In general terms detectable levels of IgM are present in blood from day 3 after the onset of symptoms and will peak by days 10-14 - this would indicate the presence of active infection, even in a person without symptoms. The levels of IgG peak later and demonstrate some form of immune response to the COVID-19 infection. As this is such a novel & new virus, clinical and scientific experience as to the exact nature of the immune response to COVID-19 is still being gathered.



10. **How does this test compare with a PCR test?**

The COVID-19 IgG/IgM Rapid Test Cassette has been compared with PCR. Specimens from patients with confirmed COVID-19 status (by PCR) were compared against the same specimens tested using the COVID-19 IgG/IgM Rapid Test Cassette.

11. **Can you get a false positive result?**

It is possible to get a false positive result if you have had a past or present infection with a non-COVID-19 coronavirus strain. For this reason, RT-PCR is recommended in conjunction with clinical symptoms to confirm a patient's current status.

12. **Can you get a false negative result?**

It is possible to get a false negative result, this is because the level of anti bodies present in each whole blood sample varies from person to person. If the level of COVID-19 antibodies present in the sample is very low, then they may not be detectable for up to 14 days from the onset of infection. For this reason, RT-PCR would be recommended in conjunction with clinical symptoms for anyone showing a negative result.

13. **How do you know if the test was conducted properly?**

The appearance of a coloured line in the control line region (C) indicates that the testing procedure was performed correctly and the proper amount of specimen was absorbed by the test media.

14. **What should you do if a positive result is indicated?**

Follow all government advice. If the IgM test line is positive seek urgent medical attention and self quarantine immediately – your status should be confirmed by a RT-PCR Test. If your IgG line is positive it indicates you have had the infection, if you have symptoms you should self-isolate.

15. **What if the test is positive but the patient doesn't display any symptoms?**

Either the patient is infected and may begin to display symptoms in the next few days, or the patient is infected but is asymptomatic. In both cases they should be treated as positive for the virus and should follow current health guidelines. Seek urgent medical attention and self quarantine immediately – your status should be confirmed by a RT-PCR Test.

16. **What should patients do if a negative result is indicated?**

A negative result indicates that the test was not able to detect the presence of antibodies to COVID-19 in the sample – it does not rule out the presence of infection. If they have symptoms then an additional RT-PCR Test would be advisable for more accurate assessment of your status.

17. **Where is the manufacturer of this test from?**

The manufacturer of this test is based in the USA.

Conclusion

The COVID-19 IgG/IgM Rapid Test Cassette is suitable for both clinical diagnosis and screening of COVID-19. Provided the test is performed correctly it has a high sensitivity, specificity and accuracy against the 2 biomarkers of COVID-19 (IgM and IgG). In addition, a variety of samples may be used in low sample volumes (single droplets of either whole blood, plasma or serum). This test is a valuable tool in the diagnosis of COVID-19 and may serve as a first line screening test before RT-PCR Testing.

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