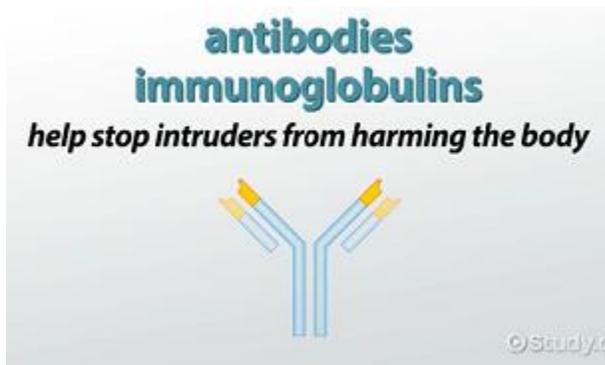


## GENERAL INFO IGM VS IGG

The 2019 n Coronavirus IgM and IgG Test is a qualitative test for the detection of IgM and IgG antibodies to 2019-nCoronwe arn of anti-2019-nCov IgM and anti-2019-nCor-IgG antibodies and can be used for the presumptive distinction between a primary and secondary Coronavirus infection. This test is for in-vitro diagnostic use only.

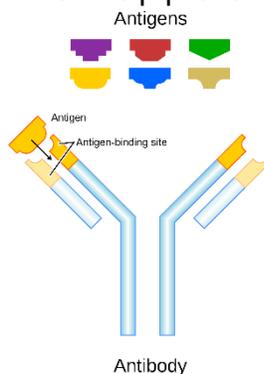
**Antibody:** An antibody, also known as an immunoglobulin, is a large Y-shaped protein produced by B- cells and used by the immune system to identify and ok perfecneutralize foreign objects such as bacteria and viruses.

They are found in the blood or other body fluids of vertebrates. ... Each antibody is different. They are all designed to attack only one kind of antigen (in practice, this means virus or bacteria).



## Antigen

The definition of antigen is a harmful substance which enters the body which causes the body to make antibodies as a response to fight off disease. An example of an antigen is a common cold virus which causes the body to make antibodies which help prevent the person from getting sick.



**Our Covid 19- test is an ANTIBODY**

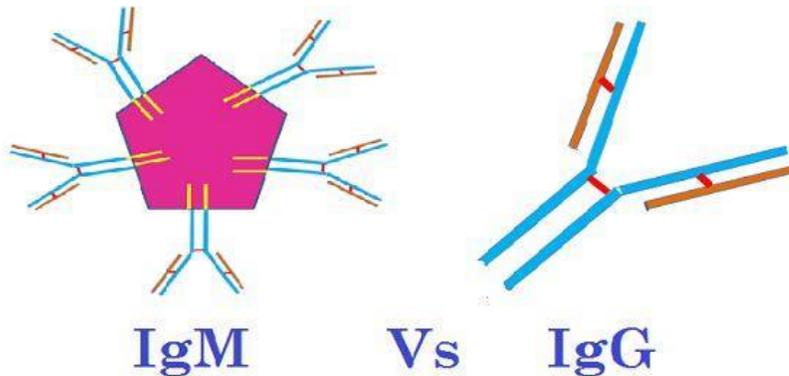
**TEST Reading the results:**

### **IgG Definition**

Immunoglobulin G (IgG) is a type of antibody. Representing approximately 75% of serum antibodies in humans, IgG is the most common type of antibody found in blood circulation

### **IgM Definition:**

Immunoglobulin M (IgM) is one of several isotypes of antibody (also known as immunoglobulin) that are produced by vertebrates. IgM is the largest antibody, and it is the first antibody to appear in the response to initial exposure to an antigen.



### **Difference between IgM and IgG**

Immunoglobulin G (IgG), the most abundant type of antibody, is found in all body fluids and protects against bacterial and viral infections. Immunoglobulin M (IgM), which is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection.

Positive IgM and IgG tests for dengue antibodies detected in an initial blood sample mean that it is likely that the person became infected with dengue virus within recent weeks. **If the IgG is positive but the IgM is low or negative, then it is likely that the person had an infection sometime in the past.**

### **Why is IgG better than IgM?**

IgG antibodies differ from IgM antibodies in their molecular size, electrical charge and anti- genic properties. It was pointed out that antibodies of the IgM class are more efficient than those of the IgG class in the agglutination of erythrocytes and bacteria

**IgG positive** : control line C and IgG line are visible on the reagent cassette. The results showed that IgG antibody was positive. **This indicates that the patient is in the recovery stage of infection.**

**IgM positive** : control line C and IgM line are visible on the reagent cassette. IgM antibody was positive, **indicating that the patient was in the acute stage of infection**

**IgM and IgG positive** : control line, IgM line and IgG line are clearly visible on the reagent cassette. IgM and IgG antibodies were positive. **It indicates that the patient is in the acute late stage of infection.**

**Negative** : the control line is the only visible line in the reagent cassette No IgG or IgM antibody was detected. The results do not exclude infection. If symptoms persist, a new sample should be taken from the patient within 3-5 days and retested.

**Invalid test results** : if the control line does not appear in the test bar, the test result is invalid regardless of whether there are other visible lines in the test bar. Retest with a new reagent cassette.

The general immune response to this virus includes the production of IgM antibodies by the 5th day of symptoms which remain in the circulatory system for 30-60 days. IgG antibodies appear by the 14th day of infection and persist for life. A secondary infection also induces an IgM antibody response after 20 days of infection and IgG antibodies rise within 1-2 days after the onset of symptoms. Therefore, patients with secondary infections will have a positive IgG result usually with a positive IgM result.

Thus, the use of a reliable and sensitive rapid serological test that can simultaneously detect the presence of anti-coronavirus IgG and IgM antibodies is of great clinical utility. 2019 n Corona virus IgM and IgG Test provides an excellent methodology for specifically detecting anti-n Corona virus IgG and IgM antibodies. The presence of high titers of IgG antibodies does not interfere with the detection of IgM antibodies in the sample. By using a mixture of recombinant Nucleocapsid protein and spike proteins, the test is able to detect 2019 nCoronavirus infection.

## **Product Questions**

### **What type of test is our CoVid-19 test?**

The 2019 n Coronavirus IgM and IgG Test is a qualitative test for the detection of IgM and IgG antibodies to 2019-nCoronavirus in human serum, plasma or whole blood. The test provides a differential detection of anti-2019-nCov IgM and anti-2019-nCor-IgG antibodies and can be used for the presumptive distinction between a primary and

secondary Coronavirus infection. This test is for in-vitro diagnostic use only.

It's an antibody test.

**Is this test CLIA Waived, can we get reimbursed?**

No, it is not CLIA waived. There is no reimbursement.

**How long would it take to get CLIA or reimbursement approval?**

We don't know.

**Does a provider need to report the results from our test?**

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

For any non negative results - the patient must be confirmed by a laboratory test before reporting to the CDC.

**Are these tests FDA approved?**

We are currently providing these tests under FDA's - EUA. Emergency Use.

**Please refer to our Clinical Study page for the accuracy rates of our tests.**

in regards to PCR Test- from what we know may produce false negatives due to laboratory error or insufficient amount of viral material collected from the patient. Samples that are stored or handled improperly also result in false negatives. Tests may result in false negatives if the patient is tested too early in the course of infection and there is insufficient amount of virus to be detected. Improper sampling may result in a false negative.

**What is included in each kit?**

- 1 Covid-19 Cassette Test
- 1 dropper (pipette)
- 1 buffer bottle for every 25 tests (4ml total)

**not included:**

Lancet

Alcohol pad  
Bandage

### **What is the detection time?**

The general immune response to this virus includes the production of IgM antibodies by the 5th day of symptoms which remain in the circulatory system for 30-60 days.

### **Do we provide any controls?**

No

### **Can we provide any additional buffer solutions?**

no we cant. There is one buffer bottle included for every 25 tests. Each bottle contains 4ML of the solution. we are not able to provide any additional ones.

### **Can these tests indicate to some capacity if someone has been exposed but if they are immune?**

We are not in a position to answer this question. The only guidance we have is from our manufacturer that is included below.

Please note our Covid -19 cassette test is only for preliminary screening, it is not a conirmation reagent. It should only be used under the guidance of professional/medical administrators.

As with all diagnostic tests, a definite 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.

**IgG positive** : control line C and IgG line are visible on the reagent cassette. The results showed that IgG antibody was positive. **This indicates that the patient is in the recovery stage of infection.**

**IgM positive** : control line C and IgM line are visible on the reagent cassette. IgM antibody was positive, **indicating that the patient was in the acute stage of infection**

**IgM and IgG positive** : control line, IgM line and IgG line are clearly visible on the reagent cassette. IgM and IgG antibodies were positive. **It indicates that the patient is in the acute late stage of infection.**

**Negative** : the control line is the only visible line in the reagent cassette No IgG or IgM antibody was detected. The results do not exclude infection. If symptoms persist, a new sample should be taken from the patient within 3-5 days and retested.

### Do we need to confirm positive IGG and IGM, or just IGM?

Please note our Covid -19 cassette test is only for preliminary screening, it is not a confirmation reagent. It should only be used under the guidance of professional/medical administrators.

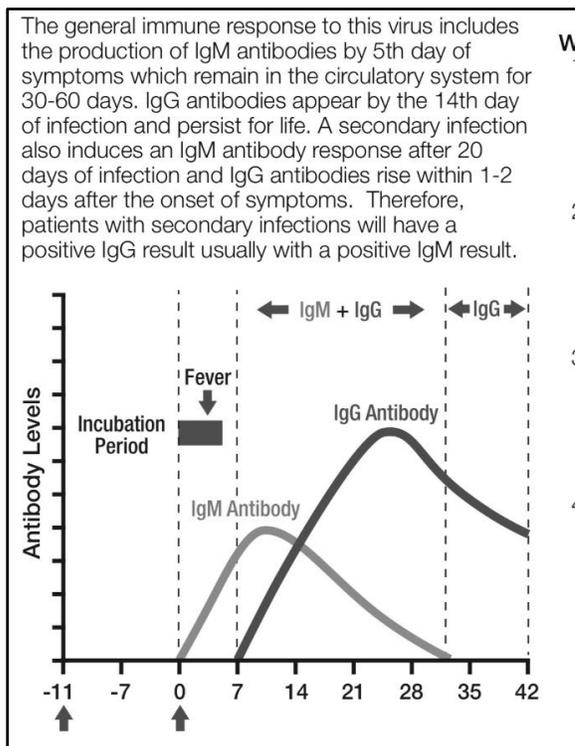
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## **General Questions**

### **What is a medical professional?**

Title 21 of the Federal Regulations for the FDA use this definition: (g) *Health professionals* means practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using a medical device for human use.

