

# FACT SHEET FOR PATIENS



## COVID-19 IgG/IgM Dual Antibody Test

### – COVID-19 IgG/IgM Dual Antibody Test – dAb ImmunoTech, Inc.

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- You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the COVID-19 (SARS-CoV-2) IgG/IgM Dual Antibody Test.
- This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

#### 1. What is Coronavirus?

Coronaviruses (CoV) are a family of single-stranded positive-sense RNA viruses that infect animals and humans. Several known coronaviruses are circulating in animals that have not yet infected humans. These are classified into 4 genera based on their host specificity. There are seven known types of CoVs. Coronavirus has caused two large-scale pandemics in the last two decades, SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome) outbreaks in 2002 and 2012 respectively occurred when the virus crossed-over from animals to humans causing significant mortality.

#### 2. What is the COVID-19?

More recently, Coronavirus Disease 2019 (COVID-19) is defined as illness caused by a novel coronavirus now called Severe Acute Respiratory Syndrome Coronavirus 2

(SARS-CoV-2; formerly called 2019-nCoV), which was first identified amid an outbreak of respiratory illness cases in Wuhan City, Hubei Province, China. It was initially reported to the WHO on December 31, 2019. On January 30, 2020, the WHO declared the COVID-19 outbreak a global health emergency. On March 11, 2020, the WHO declared COVID-19 a global pandemic, its first such designation since declaring H1N1 influenza a pandemic in 2009. Patients with SARS-CoV-2 report a mild to severe respiratory illness with viral pneumonia cases and clinical manifestations were fever, fatigue, cough, and other symptoms which can rapidly develop into severe pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders and etc., and is life-threatening and deadly infectious disease.

### **3. What is the SARS-CoV-2 IgG/IgM Dual Antibody Test?**

The COVID19 IgG/IgM Dual Antibody Test is a single use qualitative Lateral Flow ImmunoAssay to detect and differentiate both circulating IgM and IgG antibodies to SARS-CoV-2 in whole blood, serum, or plasma specimens from individuals with signs and symptoms of infection who are suspected of COVID-19 by a healthcare provider. The COVID19 IgG/IgM Dual Antibody Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the COVID19 IgG/IgM Dual Antibody Test should not be used as the sole basis for diagnosis.

### **4. What do I need to know about COVID19 IgG/IgM Dual Antibody testing?**

Individual COVID19 IgG/IgM Dual Antibody Test can detect the presence of antibodies in the blood of people believed to have been infected with COVID-19. Antibodies are produced over days to weeks after infection with the virus. Tests to detect antibody responses to COVID-19 in the population will be critical to support the development of vaccines, and to add to our understanding of the extent of infection among people who are not identified through active case finding and surveillance efforts, the attack rate in the population, and the infection fatality rate. The strength of antibody response depends on several factors, including age, nutritional status, severity of disease, and certain medications or infections like HIV

that suppress the immune system.

In the weeks after exposure to COVID-19, the immune system recognizes some components of the virus and begins to generate COVID-19 antibodies in order to damage, neutralize or kill it (this period is known as 'seroconversion'). These antibodies persist for human life.

## 5. Why was my sample tested?

You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

## 6. What are the known and potential risks and benefits of the test?

Testing of the samples will help find out if you may have COVID-19.

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

## 7. What does it mean if I have a positive test result?

The test has several possible results. Depending on the result, it may be more likely that you have COVID-19 and that you may need isolation to avoid spreading the virus to others. Other results may indicate you were infected previously. Your healthcare provider will work with you how to determine how best to care for you based on the test results along with other factors of your medical history, and your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also the small chance that this test can give a positive result that is wrong (a false positive result).

## 8. What does it mean if I have a negative test result?

A negative test result means that the antibodies to the virus that causes COVID-19 was not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19.

A negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

## 8. Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).