Dear Patient:

You are being given this Fact Sheet because your blood has been tested for evidence of SARS-CoV-2 virus infection. This testing was being done because your healthcare provider believes you may have been exposed to the virus. The test used on your specimen is called the COVID-19 IgG/IgM Rapid Test, which is a laboratory test designed to help determine if you have recently been infected with novel coronavirus (SARS-CoV-2).

This Fact Sheet contains information to help you understand the risks and benefits of using the COVID-19 IgG/IgM Rapid Test. You may want to discuss with your healthcare provider the risks and benefits described in this Fact Sheet and any additional questions you may have.

What is SARS-CoV-2 and COVID-19?

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

Coronavirus disease (COVID-19) is a new strain that was discovered in 2019 and has not been previously identified in humans. COVID-19 is caused by infection from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 virus).

Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. On March 11, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization (WHO).

What is the COVID-19 IgG/IgM Rapid Test?

The COVID-19 IgG/IgM Rapid Test is a laboratory test designed to detect proteins the human body makes to fight a SARS-CoV-2 virus infection. These proteins, called antibodies, appear in the blood starting soon after the start of COVID-19 illness. If the COVID-19 IgG/IgM Rapid Test detects these antibodies, the test is positive (i.e., reactive). If the COVID-19 IgG/IgM Rapid Test does not detect these antibodies, the test is negative (i.e., non-reactive).
What are the known and potential risks and benefits of COVID-19 IgG/IgM Rapid Test?

Besides possible discomfort or other complications that can happen when your sample(s) are collected, there is a risk that the test result is incorrect (see below for more information). However, if the resulting test is positive, it could potentially be an early indicator that you may have contracted the SARS-CoV-2 virus. Additional molecular testing for SARS-CoV-2 will be necessary to confirm a positive or negative result.

If this test is positive, does it mean that I have COVID-19 virus infection?

If you have a positive result, it is likely that you have had a recent SARS-CoV-2 virus infection. It is possible that you may have had a recent SARS-CoV-2 virus infection and not have any symptoms. There is a chance that this test can give a positive result that is wrong; this is called a “false positive” result. There are some other very closely related viruses that can cause the human body to produce antibodies that may cause the test to be positive.

If this test is negative, does it mean that I do not have a COVID-19 virus infection?

Even if you have a negative test result, you may have been infected with SARS-CoV-2 virus. If your sample was collected just after you became ill, it is possible that your body had not yet had enough time to make antibodies for the test to measure. In this situation, your healthcare provider should also take a nasopharyngeal swab for molecular testing. Your healthcare provider will help you to interpret your test results and work with you to continue to monitor your health.

Is this test FDA-approved or cleared?

The U.S. Food and Drug Administration (FDA) has not cleared or approved COVID-19 IgG/IgM Rapid Test or any other laboratory clinical test (to date) to detect SARS-CoV-2 virus infection. However, The U.S. Food and Drug Administration (FDA) has issued an Updated Policy Guidance on March 16, 2020 that enables the availability and distribution of the Aytu BioScience, Inc. (Aytu) COVID-19 IgG/IgM Rapid Test.

The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of diagnostic tests for COVID-19 virus infection, such as the COVID-19 IgG/IgM Rapid Test. FDA has allowed the distribution and use of the COVID-19 IgG/IgM Rapid Test to test for antibodies to SARS-CoV-2 virus in your specimens only for the duration of the emergency, unless it is terminated or revoked by FDA sooner.

How can I learn more?
Information about COVID-19 can be found at the CDC website:  

Any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the COVID-19 IgG/IgM Rapid Test will be made available at www.aytubio.com/.

Please also contact your health care provider if you have any questions.