Diagnostic Kit for Detection of IgG/IgM Antibody to SARS-CoV-2 Rapid Test

Legal Disclaimer

ADS Biotec
YOUR PATH TO DISCOVERY

IMPORTANT INFORMATION ABOUT THIS TEST

Please review carefully before administering the test.

TEST OVERVIEW

This test was manufactured by Jiangsu DaBo Pharmaceutical Co., Ltd. for in vitro detection of the antibodies associated with SARS-CoV-2, the virus causing coronavirus disease 2019 ("COVID-19"). In response to SARS-CoV-2 infection, your body produces specific immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies. This test is designed to confirm the presence of IgM and/or IgG antibodies in your blood. A study of 521 patients produced by Jiangsu DaBo Pharmaceutical Co., Ltd. has shown the test to be relatively precise in detecting the presence of IgM and/or IgG antibodies based on a clinical experiment conducted under strict controls and designed with blinded and controlled features. (Please see the enclosed Clinical Examination Results Sheet for a more detailed description of the study and its results.) The clinical study resulted in the following validation data:

Sensitivity	95.04%
Specificity	100%
Positive Predictive Value (PPV)	100%
Negative Predictive Value (NPV)	98.58%
Accuracy	98.88%

Despite the study's overall accuracy, your test results may be inaccurate due to improper use, failure to follow the at home testing procedure as directed, or other limitations unrelated to test performance. This may result in a false positive, false negative, or an invalid result. **Please carefully review and follow all enclosed test procedures.**

THIS IS NOT A DIAGNOSTIC TEST

This is a screening test only and may be used for the qualitative detection of the presence of IgM and/or IgG antibody to SARS-CoV-2 in blood. Please carefully review the following information relating to the test results.

Positive Test Results. A positive test result is not a clinical diagnosis of a SARS-CoV-2 infection or COVID-19. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or

to inform infection status. A COVID-19 diagnosis can only be made by a medical professional in conjunction with an evaluation of any signs and symptoms of the disease and a history of possible exposure to the virus. If you obtain a positive result from this test, please consult with your local or state health authorities for further validation and recommendations. Depending on your symptoms, you may be advised to go to the emergency room or self-quarantine at home.

Negative Test Results. A negative test results does not rule out the possibility of a SARS-CoV-2 infection or the development of COVID-19. The sensitivity of this test depends on the concentration of IgG and/or IgM antibody to SARSCoV-2 in the sample. Therefore, test samples with low antibody concentration may show negative results despite the possible presence of SARS-CoV-2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. In

addition, if you have a negative test result, but have symptoms associated with COVID-19, please consult with your local or state health authorities for further testing and recommendations.

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COVID-19 Symptoms. Regardless of the results of this test, you are advised to carefully monitor your health and physical symptoms. The common symptoms of COVID-19 are fever, cough, polypnea (rapid breathing, panting), anhelation (shortness of breath), and difficulty breathing. In more serious cases, infection may cause pneumonia, severe acute respiratory syndrome, renal failure, and even death. In accordance with guidance from the CDC, mildly ill patients may be encouraged to stay home and contact their healthcare provider by phone for guidance about clinical management. Patients who have severe symptoms, such as difficulty breathing, should seek care immediately. Older patients and individuals who have underlying medical conditions or are immunocompromised should contact their physician early in the course of even mild illness.

THIS TEST HAS NOT BEEN REVIEWED BY THE U.S. FOOD AND DRUG ADMINISTRATION (FDA). Based on the FDA's most recent publications relating to Emergency Use Authorization (EUA) issued on February 29, 2020 and updated March 16, 2020, the EUA does not apply to at home testing for SARS-CoV-2. According to its published guidance, the FDA sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection and has encouraged developers to discuss their validation of home use and/or self-collection tests with the FDA. Our supplier in the United States has been working diligently to make this test available for at home use in accordance with available state and local guidance. While the FDA does not yet have a policy for at-home testing of SARS-CoV-2, our supplier has provided information about this test, including test development, validity, efficacy, sensitivity, and test limitations, to the FDA and will work closely with the FDA throughout any future authorization process, and in addition will continue to provide accurate and up to date information about the test as it becomes available.

Contact Information

ADS Biotec Limited
40 Watt Road Hillington
Park Hillington, Glasgow,
UK G52 4RY
Phone: +44 (0)141 892 8800
Fax: +44 (0)141 883 5967
Email: info@adsbiotec.com

ADS Biotec Inc
7409 Irvington Road,
Omaha, NE 68122 USA
Phone: 402-800-3200
Fax: 402-800-3183
Email: info@adsbiotec.com
Web: www.adsbiotec.com

Increased Productivity with High Quality and Consistency