FACT SHEET FOR HEALTHCARE PROVIDERS

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

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- **Public health officials have identified cases of COVID-19 throughout the world, including in the United States. Please check the CDC webpage for the most up to date information.**

- **All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: COVID-19 (SARS-CoV-2) IgG/IgM Dual Antibody Test**

- **This rapid test checks human two antibodies, IgG and IgM to COVID-19 virus. Both antibodies to SARS-CoV-2 are produced by human body in response to the virus and is to be performed only using fingerstick whole blood, serum or plasma specimens collected from individuals suspected of COVID-19 by a 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 severed 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 Rapid Test?

The COVID-19 (SARS-CoV-2) 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 COVID-19 (SARS-CoV-2) 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 COVID-19 (SARS-CoV-2) IgG/IgM Dual Antibody Test should not be used as the sole basis for diagnosis.

4. What do I need to know about COVID-19 testing?

Individual COVID-19 (SARS-CoV-2) 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. What are the symptoms of COVID-19?

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 severed pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders and etc., and is life-threatening and deadly infectious disease.

However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

6. What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The SARS-CoV-2 lgG and lgM Rapid Test can be used to test fingerstick whole blood, serum or plasma specimens.

- The SARS-CoV-2 lgG and lgM Rapid Test can be ordered by a healthcare provider to detect if there has been an immune response to COVID-19 in the diagnosis of individuals suspected of SARS-CoV-2 infection

- The SARS-CoV-2 lgG and lgM Rapid Test is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). For additional information, refer to CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (see links provided in "Where can I go for updates and more information" section).

7. **What does it mean if the specimen tests positive for lgM and/or lgG antibodies against virus that causes COVID-19?**

A positive test result with the SARS-CoV-2 IgG/ and gM antibody Rapid Test indicates that antibodies to SARS-CoV-2 were detected, and the patient has potentially been exposed to COVID-19.

When IgM antibodies are present, they can indicate that a patient has an active or recent infection with SARS- CoV-2. IgG antibodies develop later following infection, and generally do not begin to appear until 7 – 10 days after infection. When IgG antibodies are present it, often indicates a past infection but does not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies. It is unknown how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive result for IgM or IgG may not mean that a patient's current symptoms are due to COVID-19 infection. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

The SARS-CoV-2 lgG and lgM Antibody Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the

patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19-infected patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

8. What does it mean if the specimen tests negative for IgM and/or IgG antibodies against virus that causes COVID-19?

A negative test result with this test means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection.

Patients tested early after infection may not have detectable IgM antibody despite active infection;

in addition, not all patients will develop a detectable IgM and/or IgG response to SARS-CoV-2 infection. The absolute sensitivity of the SARS-CoV-2 IgG and IgM antibody Rapid test is unknown.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID- 19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any patient suspected of COVID-19, regardless of the SARS-CoV-2 IgG/IgM Rapid test.

Risks to a patient of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

9. What is an EUA?

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he United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA 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 (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

10.Where can I go for updates and more information?

A. CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019- nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019- nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019- ncov/infection-control/index.html

B. FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency- situations-medical-devices/emergency-use-authorizations

○ INQUIRIES AND GENERAL INFORMATION

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