FACT SHEET FOR HEALTHCARE PROVIDERS

Hangzhou Biotest Biotech Co.,Ltd. **December 22, 2020**

RightSign COVID-19 IgG/IgM Rapid Test Cassette

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the RightSign COVID-19 IgG/IgM Rapid Test Cassette.

You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.

The RightSign COVID-19 IgG/IgM Rapid Test Cassetteis authorized for the detection of antibodies to SARS-CoV-2 in humanvenous whole blood (sodium heparin, EDTA, and sodium citrate), serum or plasma (sodium heparin, potassium EDTA and sodium citrate), and fingerstick whole blood.

All individuals whose specimens are tested with this test will receive the Fact Sheet for Recipients: Hangzhou Biotest Biotech Co., Ltd. – RightSignCOVID-19 IgG/IgM Rapid Test Cassette.

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

This test detects human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed on onlyhuman venous whole blood (sodium heparin, EDTA, and sodium citrate), serum or plasma (sodium heparin, potassium EDTA and sodium citrate), and fingerstick whole blood specimens.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providersis available at CDC's webpage, *Information for Healthcare Professionals*(see links provided in "*Where can I go for updates and more information?*" section).

- The RightSign COVID-19 IgG/IgM Rapid Test Cassettecan be ordered by healthcare providers to testhuman venous whole blood (sodium heparin, EDTA, and sodium citrate), serum or plasma (sodium heparin, potassium EDTA and sodium citrate), and fingerstick whole bloodto detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- The RightSign COVID-19 IgG/IgM Rapid Test Cassetteshould not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.
- The RightSign COVID-19 IgG/IgM Rapid Test Cassetteis authorized for use with all authorized specimen types inlaboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderatecomplexity tests.
- The RightSign COVID-19 IgG/IgM Rapid Test Cassette is authorized for use with fingerstick whole blood specimens at the Point of Care (POC), i.e., in

patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Please refer to theRightSign COVID-19 IgG/IgM Rapid Test Cassette instructions for use for additional information.

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

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used 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).

What does it mean if the specimen tests positive for antibodies against the virus that causes COVID-19?
A positive test result with the SARS-CoV-2 antibody test indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If IgG antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious.

It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and it is not known if they confer immunity to infection.

Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public.

Regardless of the test result, individuals should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The RightSign COVID-19 IgG/IgM Rapid Test Cassettehas been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to the patient include the following: risk of infection by exposure to persons with active COVID-19. If a recent infection is suspected a false positive result may lead to 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, or other unintended adverse effects.

Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

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

What does it mean if the specimen tests negative for 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, patients tested early after infection may not have detectable antibodies despite active infection; in addition, it is not certain that all infected patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not be used to rule out infection. Direct testing of SARS-***

CoV-2 should be performed if acute infection is suspected.

The absolute sensitivity of the RightSign COVID-19 IgG/IgM Rapid Test Cassette is unknown.

Risks to a patient of a false negative result include: restriction of activities potentially deemed acceptable for patients with evidence of an antibodyresponse to SARS-CoV-2, 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

What is an EUA?
The United States 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, andbased on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effectiveat diagnosing recent or prior infection with SARSCoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19.

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

What are the approved available alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Where can I go for updates and more information?

CDC webpages:

General:https://www.cdc.gov/COVID19
Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
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

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

Hangzhou Biotest Biotech Co., Ltd.:

Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street
Yuhang District, Hangzhou, P.R. China 311121
http://en.biotests.com.cn.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

FACTSHEET FOR RECIPIENTS

Hangzhou Biotest Biotech Co.,Ltd. **December 22,2020**

RightSign COVID-19 IgG/IgM Rapid Test Cassette

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s)is being tested or was tested for antibodies to the virus that causesCoronavirus Disease 2019 (COVID-19)using the RightSign COVID-19 IgG/IgM Rapid Test Cassette.

You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV-2, the virus that causes 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.You have the option to refuse use of this test. However, your doctor may be recommending this test because they believe it could help with your care.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 viruswhich is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all.Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death.The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link:https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

How are people tested for COVID-19?
Two kinds of tests are currently available for COVID-19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection

What is the RightSign COVID-19 IgG/IgM Rapid Test Cassette?
This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

What are the known and potential risks and benefits of the test?

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.

What does it mean if I have a positive test result?
If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. Your healthcare provider will work with you to determine how best to care for you based on the test results along with

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19is available at the CDC General webpage:**https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

other factors of your medical history, your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also a chance that this test can give a positive result that is wrong (a false positive result). Even a high-performing antibody test when used in a population without many cases of COVID-19 infection may produce as many or more false results as true results because the likelihood of finding someone who has been infected is very small.

Your healthcare provider will work with you to determine the likelihood of false result.

It is not known how long antibodies to SARS-CoV-2 will remain present in the body after infection. It is not known whether having antibodies to SARS-CoV-2 will protect you from getting infected again or help reduce the severity or duration of a future COVID-19 infection.Regardless of your test result, you should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

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 were 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. Additionally, 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.

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 canmake tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test issupported 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-19declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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