FACT SHEET FOR HEALTHCARE PROVIDERS

Anti-SARS-CoV-2 Rapid Test– Autobio Diagnostics Co., Ltd.

Distributed by Hardy Diagnostics in the United States

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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 Anti-SARS-CoV-2 Rapid Test.

The Anti-SARS-CoV-2 Rapid Test is authorized for the detection of antibodies to SARS-CoV-2 in human plasma from anticoagulated blood (Heparin/ EDTA/ sodium citrate) or serum.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: Anti-SARS-CoV-2 Rapid Test.

This test measures human S[illegible] antibodies, IgM and IgG th[illegible]re genera[illegible]as part of the human immune re[illegible]nse to the vir[illegible]and is to be performed only usi[illegible]human plasma[illegible] serum specimens.

citrate) or ser[illegible]

- The [illegible]ti-SARS[illegible] Rapid Test[illegible]n be ordered by a[illegible]althcare p[illegible]der to dete[illegible] there has beer[illegible]n adaptive im[illegible]ne re[illegible]nse to COVID-19, indic[illegible]ng a recent or p[illegible]ection.
  The [illegible]ti-SARS-CoV-2 R[illegible]id Test is only auth[illegible]in laboratories certified under the [illegible] Laboratory [illegible]provement Amendments of 1[illegible]CLIA), 42 U.S.C. §263a, to perform mod[illegible]e or high complexity tests.

Sp[illegible]mens s[illegible]ld be collected with appropriate infection cont[illegible] precautions. Current guidance for COVID-19 infec[illegible]n control precautions are available at the CDC's web[illegible]e (see links provided in "Where can I go for up[illegible]es 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).

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

A positive test result with the Anti-SARS-CoV-2 Rapid Test indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

When IgM antibodies are present, they can indicate

What are the symptoms of COVID-19?

Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, fever, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVI[illegible]19 suggests that symptoms include cough, shortnes[illegible]of breath or difficulty breathing, fever, chills, muscle[illegible]in, headache, sore throat or new loss of tast[illegible]r smel[illegible] Based on what is known about the virus th[illegible]causes COVID-19, signs and symptoms may appea[illegible]ny time from 2 to 14 days after exposure to the virus. Based on preliminary data, the med[illegible]incubation pe[illegible]d is approximately 5 days, but may r[illegible]2-14 days.

Public health officials[illegible]ve identified cases [illegible]D-19 infection throu[illegible]ut the world, including the United States, which p[illegible]es risks to p[illegible]ic health. Please check the CDC [illegible]bpage f[illegible]e most up-to-date information.

What [illegible]d to kn[illegible]bout C[illegible]D-19 testing?

C[illegible]ent infor[illegible]ion on C[illegible]D-1[illegible]or healthcare [illegible]viders is a[illegible]lable at CDC[illegible]ebpage, *Information [illegible]r Healthca[illegible]Professionals* (see links provided in [illegible]here c[illegible]go f[illegible]s and more information" se[illegible]

The A[illegible]ARS-CoV-2 Rapid Test can be used to t[illegible]uman plasma from anticoagula[illegible]blood (Heparin/ EDTA/ sodium

that an individual has a recent or prior 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 individuals 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 an individual'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 to guide patient management decisions.

The Anti-SARS-CoV-2 Rapid Test has been designed to minimize the likelihood of false positive test result However, in the event of a false positive result, immediate measures to consider could include th following: a recommendation for isolation of the individual, monitoring of household or othe close contacts for symptoms, isolation that migh mit co t with family, friends, or other potentially CO -19-infected individuals, limits in the ability to wo or other unintended adverse effects. Due to the risk of lse positive results, confirmation positive results ould be considered - using a second, nt IgG or M assay.

All laboratories usi this test must follow standard confirmatory tes g and repor g guidelines according to their appropri public h th authorities.

What does it mean if the specimen tests negative for IgM a antibo s agains irus that causes CO D-19?

A negative tes esult with thi t means that SARS-CoV- pecific antibodies were not present in the specimen ve t detection. However, a neg esult does not preclude COVID-19 infection and s ld not be used as the sole basis for treatment, patient m agement decisions, or to rule out active infection.

Individuals tested during early phase of the infection may not have detectable IgM antibody despite active infection; in addition, not all individua op a detectable IgM and/or IgG respon o SARS-C 2 infection. The absolute sensitivi of the SARS-Co IgG/IgM Rapid test is unknow

When testing is negativ he possi y of a false negative result shou e considered he contex an individual's rec exposures and the sen of clinical signs an ymptoms c sistent wit D-19. This is especia important he individual has had recent exposure OVI 19, or clinical presentation suggesti of COVI , and diagno tests for other causes c lness (e.g., er respir y illness) are negative irect testing f rus g., rt-PCR testing) should a ays be performe y individual suspected COVI 9, regardless of the Anti-SARS-CoV-2 Rapid te

Risks t individual of a false negative result include: layed ck of supportive treatment, lack of m oring c fected individuals and their household or othe lose contacts for symptoms resulting in increased risk spread of COVID-19 within the community, or othe intended adverse events.

What is an EUA?

The 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).

Where can I go for updates and more information?

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

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: (includes links to recipient fact sh and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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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**