This Fact Sheet informs you of the significant known and potential risks and benefits of the Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM Rapid Test as described by the US Food and Drug Administration (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests).

The Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM Rapid Test is authorized for use on serum, plasma or venipuncture whole blood specimens from people suspected of Coronavirus Disease 2019 (COVID-19) by their healthcare provider.

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

### What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). 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.

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

### 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 Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM Rapid Test can be used to test serum, plasma (EDTA or citrate), or venipuncture whole blood specimens.

- The Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM 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 Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM Rapid Test is only for healthcare professionals and professionals at point of care sites.

This test measures human SARS-CoV-2 antibodies, IgM and IgG that are generated as part of the human immune response to the virus and is to be performed only using serum, plasma, or venipuncture whole blood specimens collected from individuals suspected of COVID-19 by a healthcare provider.

**FACT SHEET FOR HEALTHCARE PROVIDERS**
Clungene® SARS-COV-2 VIRUS (COVID-19) IgG/IgM
Rapid Test Cassette

Coronavirus
Disease 2019
(COVID-19)

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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).

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

A positive test result with the Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM 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.

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 Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM 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.

## 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 accuracy

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of the Clungene SARS-COV-2 VIRUS (COVID-19) IgG/IgM Rapid Test reported on the Instructions for Use is 93.41%; however the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) has not been absolutely determined for lateral flow chromatographic immunoassays which can detect antibodies against the SARS-CoV-2 virus.

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 Clungene SARS-COV-2 VIRUS (COVID-19) 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.

## 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 patient fact sheet 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**