FACT SHEET FOR HEALTHCARE PROVIDERS

Visby Medical, Inc. **August 31, 2021**

Visby Medical COVID-19

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 Visby Medical COVID-19.

The Visby Medical COVID-19 is authorized for use with nasopharyngeal, anterior nasal, or dual nostril mid-turbinate (mid-turbinate) nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Visby Medical, Inc. - Visby Medical COVID-19.

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 jurisdictions website 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).

This test is to be performed only using nasopharyngeal, anterior nasal, or mid-turbinate nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.

- The Visby Medical COVID-19 can be used to test nasopharyngeal, anterior nasal or mid-turbinate nasal swabs collected by a healthcare provider (HCP), or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting).
- The Visby Medical COVID-19 should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Visby Medical COVID-19 can also be used to test up to five individual samples from anterior nasal or mid turbinate nasal swabs (self-collected) or nasopharyngeal, anterior nasal, or mid-turbinate nasal swabs collected by a healthcare provider using individual vials containing transport media. Testing of non-pooled specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.
- Testing of pooled samples is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests only.

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 the virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The Visby Medical COVID-19 has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. 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 patients, limits in the ability to work, 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 the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 RNA was 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 or patient management decisions. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via Visby Medical COVID-19.

Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. Your interpretation of negative results should take into account clinical and epidemiological risk factors.

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. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative.

If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing using a new sample with a sensitive method or without pooling should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test 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.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARSCoV-2 and their prevalence, which change over time.

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, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing 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).

What are the approved available alternatives?
Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA ca be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/m ical-device-databases. A cleared or approved test sh ld be used instead of a test made available under an EU when appropriate and available. FDA h issued E As for other tests that can be found at: https://www.fda.gov/emergency-p paredness-and-response/mcm-legal-regulatory nd-polic framework/emergency-use-au rizati .

Where can I go for updates and more information?

CDC webpages:
General: https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Profess nals:
https://www.cdc.go coronavirus/20 -nCoV/hcp/index.html
Information fo Labo ories:
https://www c.gov/cor virus/2 9-nCoV/lab/index.html
Laborato Biosafety: http w.cdc.gov/coronavirus/2019-nCoV/l biosafet guidelines html
Isolation ecs tions in Healthcare Settings:
htt //www .gov/infe oncontrol/guidelines/isolation/index.html
Sp imen Co tio https://www.cdc.gov/coronavirus/2019-nC //guidelines- cal-specimens.html
Inf n Control: https://www.cdc.gov/coronavirus/2019-n /php/ n-control.html

FDA webpages:
eneral: www.fda.gov/novelcoronavirus
UAs:(includes links to patient fact sheet and manufacturer's nstructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

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