This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Biomeme SARS-CoV-2 Real-Time RT-PCR Test.

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test is authorized for use with certain respiratory specimens collected from individuals consistent with the Emergency Use Authorization (EUA).

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Biomeme, Inc. – Biomeme SARS-CoV-2 Real-Time RT-PCR 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, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. 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, and the median incubation period 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 at the end of this document.

Public health officials have identified cases of COVID-19 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) 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 Biomeme SARS-CoV-2 Real-Time RT-PCR Test can be used to test nasopharyngeal, nasal, and oropharyngeal swab specimens, and nasopharyngeal wash/aspirate or nasal aspirate specimens in individuals suspected of COVID-19 by their healthcare provider.
- The Biomeme SARS-CoV-2 Real-Time RT-PCR Test can also be used to test up to 10 human anterior nasal swabs placed in a single vial containing transport media after being collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from individuals without symptoms or other reasons to suspect COVID-19, when tested as part of a serial testing program including testing at least once per week.
- The Biomeme SARS-CoV-2 Real-Time RT-PCR Test can also be used to test pooled samples containing aliquots of transport media from up to 10 individual human anterior nasal swab specimens that were collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from individuals without symptoms or other reasons to suspect COVID-19 and placed in individual vials containing transport media, when tested as part of a serial testing program including testing at least once per week.
- The Biomeme SARS-CoV-2 Real-Time RT-PCR Test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

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 the virus that causes COVID-19, appropriate personal protective

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
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 in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test 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 individuals with COVID-19, 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.

Individuals included in a pool that returns a positive or invalid result should be treated as a presumptive positive unless or until they receive a negative result when re-tested individually. However, as most individuals in a positive pool will likely receive a negative result when re-tested individually, they should isolate until receiving a negative result when re-tested individually and should not be cohort with other individuals who have received a positive or presumptive positive result.

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 SARS-CoV-2 infection to make an accurate diagnosis via Biomeme SARS-CoV-2 Real-Time RT-PCR Test. In addition, asymptomatic people infected with COVID-19 may not shed enough virus to reach the limit of detection of the test, giving a false negative result. In the absence of symptoms, it is difficult to determine if asymptomatic people have been tested too late or too early. Therefore, negative results in asymptomatic individuals may include individuals who were tested too early and may become positive later, individuals who were tested too late and may have serological evidence of infection, or individuals who were never infected.

Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity or increased interference 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 with an alternative method should be considered by healthcare providers in consultation with public health.
advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. 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:**
- Isolation Precautions in Healthcare Settings: [https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html](https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html)

**FDA webpages:**
- General: [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

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