This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits product.

The Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits product is direct to consumer product for testing of anterior nasal swab specimens collected at home using either the Everlywell COVID-19 Test Home Collection Kit DTC, the Kroger Health COVID-19 Test Home Collection Kit or the GetMyDNA COVID-19 Test Home Collection Kit.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Individuals: Gravity Diagnostics, LLC - Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits.

What are the symptoms of COVID-19? Many individuals 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.

This test is to be performed only using anterior nasal swab specimens collected at home using either the Everlywell COVID-19 Test Home Collection Kit DTC, the Kroger Health COVID-19 Test Home Collection Kit or the GetMyDNA COVID-19 Test Home Collection Kit.

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 Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits is direct to consumer product for testing of anterior nasal swab specimens collected at home using either: (1) the Everlywell COVID-19 Test Home Collection Kit DTC when used consistent with its authorization; (2) the Kroger Health COVID-19 Test Home Collection Kit when used consistent with its authorization, or (3) the GetMyDNA COVID-19 Test Home Collection Kit when used consistent with its authorization.

- The Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits is only authorized for use at Gravity Diagnostics, LLC, located at 632 Russell Street, Covington, KY 41011 and 812 Russell Street, Covington, KY 41011, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

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).

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 (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 Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits product 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. The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is

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Coronavirus Disease 2019 (COVID-19)
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 can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-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:**
- General: https://www.cdc.gov/COVID19

**FDA webpages:**
- General: www.fda.gov/novelcoronavirus

**Gravity Diagnostics, LLC:**
632 Russell Street
Covington, KY 41011

**Customer Support:**
855.841.7111
info@gravitydiagnostics.com

**Technical Support:**
859.309.8683
Techsupport@gravitydiagnostics.com

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