MERCY URGENT CARE

You are being given this information because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the ID NOW COVID-19 test.

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. Symptoms include: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

What is the ID NOW COVID-19 test?

The test is designed to detect the virus that causes COVID-19 in respiratory specimens (e.g. nasal or oral swabs.)

Who can get the ID NOW COVID-19 test?

To qualify for the ID NOW COVID-19 test, at Mercy Urgent Care, patients must meet two criteria:

1. Healthcare Workers/Essential Worker (e.g. police, fire fighters, EMS) or High risk persons or their direct caregiver(s):

- Age 65 and older
- Those the CDC designates are at high risk for severe illness due to the following medical conditions, regardless of age:
  - Cancer
  - Chronic kidney disease
  - COPD (chronic obstructive pulmonary disease)
  - Immunocompromised state
  - Obesity
  - Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
  - Sickle cell disease
  - Type 2 diabetes mellitus
  - Others chronic conditions such as asthma, hypertension and Cystic Fibrosis

2. Experiencing two or more of the symptoms (listed above) for at least 24 hours.

What are the potential risks and benefits of the test?

Potential risks include: Possible discomfort during sample collection and possible incorrect test result.

Potential benefits include: Results which can help your healthcare provider make informed recommendations about your care. The results of this test may help you and health officials limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19. You may be placed in isolation to avoid spreading the virus to others. There is a very small chance this test can give a positive result that is wrong (false positive). Your healthcare provider and local health department will work with you on a plan of care.

What does it mean if I have a negative test result?

A negative test result means the virus that causes COVID-19 was not found in your sample, and that COVID-19 likely did not cause your recent illness. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. Your healthcare provider will consider the test result together with all other aspects of your medical history and exam. It is important that you work with your healthcare provider on next steps you should take. Further testing, sent to a lab, is recommended for those who have a negative test and have symptoms consistent with COVID-19, not otherwise explained by another illnesses, test, or known patient condition(s).

What is the sensitivity and specificity of the ID NOW COVID-19 test?

A test's sensitivity is the ability of a test to correctly identify people with the disease (true positive rate), whereas test specificity is the ability of the test to correctly identify people without the disease (true negative rate).

- Sensitivity for the ID NOW test is 95%
- Specificity for the ID NOW test is 100%

Is this test FDA-approved or cleared?

This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test 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. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by the FDA (after which the test may no longer be used.

For the most up-to-date information on COVID-19, refer to the CDC webpage: https://www.cdc.gov/COVID19