



COVID-19 VIRUS TESTING AT INDIANA REGIONAL MEDICAL CENTER

FACT SHEET FOR PATIENTS

Indiana Regional Medical Center and Indiana University of Pennsylvania have entered into a partnership to provide you with viral diagnostic tests for the COVID-19 virus using the latest technology.

You are being given this informational sheet because your sample was tested for the coronavirus causing the present pandemic, SARS CoV-2 or COVID-19, for the detection of nucleic acid extracted from the SARS-CoV-2 virus, using Real-Time PCR. The SARS-CoV-2 Real-Time PCR analysis does not test for any other viruses or pathogens

The information contained here is to help you understand the risks and benefits of this test to diagnose COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

What is COVID-19?

COVID-19 is the virus which can cause mild to severe respiratory illness that was first identified in Wuhan, China in November 2019. It has now spread globally including the entire United States. The spectrum of illness from this virus is unpredictable although some people are more vulnerable to severe illness including the elderly, people with certain preexisting conditions such as lung disease, diabetes and hypertension. It is also a greater threat to immunosuppressed patients such as those taking chemotherapy. The illness spreads most often from person to person by coughing, sneezing and close contact.

If you are having a procedure, special precautions will be followed to ensure your safety and that of the hospital staff. You will be screened for COVID-19, via nasal swab, prior to your procedure.

After getting tested for COVID-19, you will receive your results from the healthcare provider who ordered your test.

What is our test?

The test is designed to detect the virus that causes COVID-19 in respiratory specimens. It is usually obtained from the nasopharynx (back of the nasal passages) or lungs.

Why was my sample tested?

If you are scheduled to have a surgical procedure, your physician has ordered this test to make sure that you do not have COVID-19 before you have your surgery.

If you are not having surgery, you were tested because your health care provider suspects you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms such as cough, fever, difficulty breathing, loss of sense of smell, or other symptoms you may be having.

This test will help determine if you may have COVID-19.

The risks of taking the test:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result.

The benefits of taking the test:

- The results, along with other medical information can help your health care provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does a positive test result mean for me?

If you have a positive test result, it is very likely you have COVID-19. Therefore you will be placed in isolation (quarantine) to avoid spreading the virus to others. Your health care provider will work with you to determine how best to care for you based on the test results, your symptoms and your medical history

What does a negative test result mean for me?

A negative test result means that the virus that caused COVID-19 was not found in your sample. For this test for COVID-19, a negative test result for a sample collected while a person has symptoms suspected by your health care provider of being caused by COVID-19, means that this virus probably did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative). This means you could still have COVID-19 even though the test is negative. In this case your health care provider will consider the test result together with all other aspects of your medical history in deciding how to care for and advise you.

It is very important that you work with your healthcare provider to help you understand the next steps you should take.

This test has been developed under an emergency access mechanism called an Emergency Use Authorization (EUA). The FDA has allowed tests to be made available under EUA after receiving permission from the Secretary of Health and Human Services that declared that circumstances exist to justify the emergency use of in vitro diagnostic tests for the detection of the virus that causes COVID-19. This test has not gone through formal clearance by the FDA.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564 (b)(1) of the Act, 21 U.S.C. 360bbb-3 (b) (1), unless the authorization is terminated or revoked sooner.

Where can I go for updates and more information?

The most up-to-date information on COVID-19 is available at the CDC General web page:

<https://www.cdc.gov/COVID19>

In addition, please also contact your healthcare provider with any questions/concerns.

The methods and procedures of the IRMC/IUP COVID-19 test follow similar principles and procedures as tests performed by CDC (Centers for Disease Control) and by major commercial laboratories.