INDIANA
REGIONAL MEDICAL CENTER

COVID-19 Virus Testing at IRMC:

A Joint Project with Indiana University of Pennsylvania

FACT SHEET FOR PROVIDERS

We are introducing SARS-CoV 2 virus testing performed at Indiana Regional Medical Center.
This is the result of a combined project including Dr. N. Bharathan, Chairman of the Department of Biology at IUP with his staff, and the laboratory at IRMC, with the support of the Administration of IRMC.

Dr. Bharathan is a virologist who is very experienced in rt-pcr technology (reverse transcriptase polymerase chain reaction). He is able to bring his expertise and his staff to our hospital and work with our laboratory to perform rt-pcr for SARS-CoV 2 (COVID-19) here in our hospital. This is essentially the same technology used by all laboratories for detection of the virus that is causing the COVID-19 pandemic.

The test detects the virus by first extracting the viral RNA. It is then exposed to specific probe and primer nucleic acid sequences that can be transcribed to create a DNA copy of the viral genome segment. This is amplified and detected spectrophotometrically. Appropriate positive and negative controls are run for validation.

The risk of false positives is extremely small because the probes are specific to SARS-CoV 2 virus and will not be copied with any other virus including SARS-CoV 1 virus, the most closely related virus. A false positive could indicate a technical problem with the test such as a contaminated sample.

The risk of false negatives is greater. This may be due to sampling problems such as not getting good patient cooperation for a sample from the posterior nasopharynx. It may also be due to lack of virus in the nasopharynx. It is possible to clear the virus from the upper respiratory tract even with it in the lungs. It is also possible that the patient's illness is secondary to immune response to ongoing COVID-19 infection and they may have already cleared detectable virus. The patient may have delayed testing. There may also be transport problems but that is very unlikely since we will control the transport and storage of specimens.

Reference Range: SARS-CoV-2 not detected.

Interpretation of Results:

Positive for SARS-CoV-2: This indicates that RNA from SARS-CoV-2 was detected. The patient is infected with the virus and presumed to be contagious. Laboratory results should always be considered in the context of clinical information and epidemiologic data in making a final diagnosis and patient management decisions. Patient management should follow current CDC, Pennsylvania Department of Health and Indiana Regional Medical Center guidelines. While false positive results are rare, further testing including repeat viral rt-pcr, second test rt-pcr test at an alternate laboratory can be performed. Other clinical diagnoses may be considered or may introduce confounding morbidities.

Negative for SARS-CoV-2: 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. A negative result does not exclude the possibility of COVID-19.
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 presence of clinical signs and symptoms including non-respiratory 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, especially viral and bacterial pneumonia are negative.

- This test has been authorized by the FDA under an Emergency Use Authorization (EUA).
- This test has not been cleared or approved by the FDA
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens
- 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.

For further information, refer to the CDC webpage at www.cdc.gov, COVID-19 Information for Healthcare Professionals.