

DISCLAIMER

Result Information - Not Detected:

The test result includes a Negative /Not Detected result for Covid-19. The SARS COV-2 RNA was not present in this specimen above the set limit of detection. A negative result does not rule out the possibility of a Covid-19 infection and should not be an independent indicator of patient health and treatment plans. Clinical correlation with additional diagnostic information, such as patient exposure and clinical representation of symptoms, is necessary for final medical evaluation and patient treatment decisions.

Result Information - Detected:

The test result includes a Positive/Detected result for Covid-19. The SARS COV-2 RNA was present in this specimen above the set limit of detection. A positive result indicates an active respiratory infection with SARS - COV-2, which is commonly detected in respiratory specimens during the acute phase of infection. Positive results do not rule out an active bacterial infection or co-infection with other viruses. The detected agent may not be the definitive cause of infection. A positive result should not be an independent indicator of patient health. Clinical correlation with additional diagnostic information, such as patient exposure and clinical representation of symptoms, is necessary for final medical evaluation and patient treatment decisions.

Method Information:

This test was developed by ThermoFisher, validated and performed by National Labs. This test is not FDA-approved and is authorized under the FDA Emergency Utilization Act (EUA). On February 29, 2020, the FDA issued the "Policy for Diagnostics Testing in Laboratories Certified to Perform High-Complexity Testing Prior to Emergency Use Authorization for Coronavirus Disease 2019 During the Public Health Emergency." This method has been validated in accordance to all guidance regulations, with independent review by the FDA pending.

This test remains authorized during this period where existing circumstances set forward by the government justify the authorized emergency use of in vitro diagnostic tests for detection of SARS-COV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1).

The performance of this test has not been established for ongoing monitoring of the treatment of COVID-19 infection
The performance of this test has not been established for screening of blood or blood products for COVID-19 infection
The test cannot rule out diseases caused by other bacterial or viral pathogens
A licensed health care provider should provide any interpretation or recommendation for treatment based on test results