

**COVID-19 is a respiratory disease caused by infection with a new form of coronavirus (SARS-CoV-2) that has now been detected in multiple locations around the world, including the U.S. NCF DNA is supporting the public health response as part of a lab industry consortium that is working very hard to expand the availability of testing.**

Below are answers to questions about NCF DNA's testing for COVID-19, including test methodology, appropriate specimen types, specimen packaging and shipping, and test result reporting.

#### **1. Does NCF DNA offer testing to detect the presence of the 2019 novel coronavirus?**

**A:** Yes. NCF DNA's 2019 Novel Coronavirus (COVID-19) testing is available for ordering by physicians and other authorized health care providers anywhere in the U.S. The test detects the presence of the underlying virus (SARS-CoV-2) that causes COVID-19 and is for use with patients who meet current guidance for evaluation of infection with COVID-19.

#### **2. Can I have COVID-19 testing done at a NCF DNA service center?**

**A:** No. NCF DNA does not collect specimens for COVID-19 testing. Test specimens for COVID-19 must be collected by a physician or other healthcare provider.

#### **3. What is the test methodology for 2019 Novel Coronavirus (COVID-19) testing?**

**A:** The COVID-19 tests performed by NCF DNA are qualitative assays using PCR technology.

#### **4. Are you performing the CDC or lab developed test (LDT) for COVID-19?**

**A:** Yes. Beginning Monday, March 23, 2020, NCF DNA is performing the lab developed test (LDT) protocol test for COVID-19.

#### **5. What are the differences between the different versions of the COVID-19 tests offered by NCF DNA?**

**A:** The tests have the same ordering (including the same test code), specimen collection and processing requirements, test result reporting, billing, and all are RT-PCR tests.

The primary difference between the tests is that they are performed on different platforms and using different reagents.

Being able to perform different versions of the test provides NCF DNA with flexibility, resiliency, and the ability to adapt to best meet the need for increased capacity.

#### **6. Can physicians or facilities choose which version of the test is performed for their patients?**

**A:** No. Each version of the COVID-19 test performed by NCF DNA delivery high-quality results for the qualitative detection of the virus that causes COVID-19. Maintaining flexibility over which test to perform for a given specimen allows NCF DNA to best support the need for increased testing capacity.

#### **7. Who can order NCF DNA's 2019 Novel Coronavirus (COVID-19) testing?**

**A:** Testing can be ordered only by physicians or other authorized health care providers anywhere in the U.S. Individuals seeking testing for COVID-19 should consult with their physician or healthcare provider, who may order the test if they determine the individual meets testing criteria. Self-ordered testing for COVID-19 is not available.

#### **8. What are acceptable samples types for 2019 Novel Coronavirus (COVID-19) testing?**

**A:** The following are acceptable sample types, all preferably shipped frozen:

- Oropharyngeal (OP) collection in viral transport medium;
- Nasopharyngeal (NP) swab in viral transport medium;
- OP or NP washes/aspirates in sterile cups; and

#### **9. How should samples be shipped?**

**A:** Samples/specimens should be shipped frozen at -20°C (preferred); refrigerated specimens acceptable (if received for testing within 72 hours of collection); room temperature swabs are acceptable (if received within 24 hours of collection).

#### **10. How should specimens be collected?**

**A:** Detailed instructions for NP and OP specimen collection, including illustrated guides, can be found on our website, [NCFDNA.com/COVID-19](https://www.ncfdna.com/COVID-19).

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**11. What are the criteria for sample rejection?**

- A:** Unacceptable specimens include those that are:
- Swabs with calcium alginate or cotton tips;
  - swabs with wooden shafts;
  - swabs with preservatives;
  - refrigerated samples greater than 72 hours old;
  - room temperature swabs greater than 24 hours old;
  - improperly labeled;
  - grossly contaminated;
  - broken or leaking transport device;
  - collection with substances inhibitory to PCR including heparin, hemoglobin, ethanol, EDTA concentrations >0.01M.

**12. How long will it take NCF DNA to report results back?**

- A:**
- Up to 3-4 days from the pickup of the specimen to release of the test result.
  - After the specimen is received at the lab, it takes approximately 24 hours to complete the testing process. The time to complete testing is generally the same for any lab that is performing testing for COVID-19 using RT-PCR technology.
  - Test results are most typically reported electronically, which generally allows for faster delivery.
  - Due to the need for rapid response, positive results are reported to the ordering provider by telephone.
  - We are also reporting test results to public health authorities as required.
  - In some cases, additional time should be allowed for additional confirmatory or additional reflex tests.

**13. How will ordering physicians be notified of positive results?**

- A:** Positive results are treated as a critical result and called to the ordering physician or health care provider. Indeterminate results and negative results will not be called.

**14. Will positive COVID-19 results be reported to local and state public health entities?**

- A:** NCF DNA will report positive COVID-19 results to the appropriate public health agency in accordance with applicable requirements; however, health care providers may also be required to report positive patients to the appropriate public health agency.

**15. Are positive tests being sent to CDC or state health labs for confirmatory testing?**

- A:** No confirmation of test results is required for the COVID-19 testing performed by NCF DNA.

**16. Does a negative result from NCF DNA's testing for COVID-19 mean that a patient is definitely not infected?**

- A:** Not necessarily. NCF DNA's testing for COVID-19 detects the virus directly, within the established limits of detection for which it was validated. A positive result is considered definitive evidence of infection. However, a negative result does not definitively rule out infection. As with any test, the accuracy relies on many factors:
- The test may not detect virus in an infected patient if the virus is not being actively shed at the time or site of sample collection.
  - The amount of time that an individual was exposed prior to the collection of the specimen can also influence whether the test will detect the virus.
  - Individual response to the virus can differ.
  - Whether the specimen we receive was collected properly, sent promptly, and packaged correctly.

Test results are a critical part of any diagnosis, but must be used by the clinician along with other information to form a diagnosis.

**17. Can Respiratory Pathogen Profile testing be ordered to rule out COVID-19?**

- A:** No, but if the COVID-19 is anything other than positive, the Respiratory Pathogen Profile (RespiraPath) test will be performed as it may be useful to detect other suspected respiratory tract infections, such as influenza, parainfluenza, and respiratory syncytial virus.

**18. What are the symptoms of COVID-19?**

- A:** Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (eg, cough, difficulty breathing). Additional criteria for testing include close contact with a laboratory-confirmed COVID-19 patient within 14 days of symptom onset, or a history of travel from affected geographic areas within 14 days of symptom onset.

More information about risk evaluation criteria can be found on the [Centers for Disease Control and Prevention website](#) and may also be available from state or local health authorities.