FAQ | PGxCOVID Novel Coronavirus (COVID-19) Test

COVID-19 is a respiratory disease caused by infection with a new form of corona virus (SARS-CoV-2) that has now been detected around the world, including the United States.- Pro-GeneX Clinical 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 the answers to questions about Pro-GeneX Laboratories, Inc. test for COVID-19, including test methodology, appropriate specimen types, specimen packaging and shipping, and test result reporting.

Q: Does Pro-GeneX Clinical offer a test to detect the presence of COVID-19?

A: Yes. Pro-GeneX Laboratories, Inc. COVID-19 Test is available for ordering by physicians and other authorized health care pro-viders anywhere in the United States. The test detects the presence of the underlying virus (SARS-CoV-2), that causes COVID-19, and should only be used with patients who meet current medical guidance for evaluation of infection with COVID-19.

Q: What is the test methodology for COVID-19?

A: Pro-GeneX Laboratories, Inc.COVID-19 test is qualitative in nature (positive or negative) and uses PCR technology, developed by ThermoFisher Scientific. Pro-GeneX Clinical has validated the COVID-19 test according to high-complexity testing requirements set forth by ThermoFisher and the Clinical Laboratory Improvement Amendments. Our COVID-19 test is pending the Food and Drug Administration's independent review under its Emergency Use Authorization authority for COVID-19.

ThermoFischer Scientific Test Kit:
https://www.thermofisher.com/us/en/home/clinical/clinical-genomics/pathogen-detection-solutions/coronavirus-2019-ncov/genetic-analysis.html

The new kit is designed to rapidly differentiate SARS-CoV-2 from 21 other pathogens implicated in serious respiratory syndromes.

Q: Who can order Pro-GeneX Laboratories, Inc. COVID-19 test?

A: Only a physician other authorized health care provider can order this test, and it can be ordered from anywhere in the United States. Individuals seeking testing for COVID-19 should consult with their physician or healthcare provider and work with them to determine if current medical criteria exist for testing. At this time, consumer or self-ordered testing for COVD-19 is not available.

Q: What are acceptable sample types for COVID-19 testing?

A: The following are acceptable sample types and its preferable to ship them frozen:

- **Nasopharyngeal (NP) swab submitted in viral transport media, which is a preferred sample type.**
- **Oropharyngeal (OP) swab submitted in viral transport media, which is a preferred sample type.**
- Oropharyngeal (OP) aspirate or washing submitted in a sterile, leak-proof, screw cap sputum collection cup or sterile dry container.
- Nasopharyngeal (NP) aspirate or washing submitted in a sterile, leak-proof, screw cap sputum collection cup or sterile dry container.
- Bronchoalveolar lavage (BAL) or bronchial wash, 2-3 mL collected into a sterile, leak-proof, screw cap sputum collection cup or sterile dry container.

Q: How should COVID-19 test samples be shipped?

A: The preferred method of shipment is frozen samples. However, samples can be shipped refrigerated at 2-8°. Room temperature samples can be accepted, but only if specimen is tested within 72 hours from collection.

Q: What are the criteria for sample rejection?

A: Unacceptable specimens include those that are:

- Improperly labeled.
- Contaminated.
- Broken or leaking.
- Improperly collected.
- Shipped at room temperature.
- Samples that exceed the 72- hour stability.

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Q: How long will it take Pro-GeneX Laboratories, Inc. to report back results?

A: Up to 1-2 days from the pickup of the specimen to release 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 COVD-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 being reported to the ordering provider by telephone and will be followed by electronic/papered results.
- We are also reporting test results to public health authorities as required by law.
- In some cases, additional time should be allowed for additional confirmatory or additional reflex tests.

Q: How will ordering physicians be notified of positive COVID-19 test results?

A: Positive results are critical results and will treated as such. Pre-GeneX clinical personnel will call the ordering physician or health care provider. Indeterminate results and negative results will not be reported by phone.

Q: Will positive COVID-19 test results be reported to local and state public health entities?

A: Pro-GeneX Clinical will report positive COVD-19 test results to the appropriate public health agency in accordance with applicable laws and regulations. NOTE: In some areas, physicians/health care providers may also be required by law to report COVID-19-positive patients to a state and/or local public health agency.

Q: Will Pro-GeneX Clinical send positive COVID-19 tests to the CDC or state health labs for confirmatory testing?

A: No. The Pro-GeneX Clinical COVID-19 test uses a multi-target PCR that provides definitive reporting for the detection of SARS-CoV-2, which causes COVID-19. Under FDA guidance, the first 5 positive (and first 5 negative) results from Pro-GeneX Clinical testing are to be confirmed using an EUA-authorized assay. Otherwise, confirmatory testing by the CDC or state health labs is not required at this time.

Q: Does a Negative result from Pro-GeneX Laboratories, Inc. test for COVID-19 mean that a patient is not infected?

A: Not necessarily. Pro-GeneX Laboratories, Inc. COVID-19 assay detects the virus directly, within the established limits of detection for which the test is validated. **A positive result is considered definitive evidence of infection**. **<u>However, a negative result does not definitively rule out infection.</u>** As with any test, the accuracy of the result relies on many factors:

- The test may might 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 to the virus 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 physician/healthcare provider along with other information to form a diagnosis.

Q: Can I have COVID-19 testing done at a Pro-GeneX location?

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

Q: Can Respiratory Pathogen Profile, PCR (139650) testing be ordered to rule out COVID-19?

A: No. Respiratory Pathogen Profile, PCR (139650) does not detect COVID-19, but it may be useful to detect and rule out other suspected respiratory tract infections, such as influenza, parainfluenza, and respiratory syncytial virus. Physicians and other healthcare providers may order this test if medically necessary, meaning the testing has a connection to the nature of the treatment provided.

Q: What are the symptoms of COVID-19?

A: Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Additional criteria 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 symptoms onset. Other symptoms are possible; Check the CDC's website regularly: https://www.cdc.gov/coronavirus/2019-nCoV/index.html.

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