Q&A | LABCORP 2019 NOVEL CORONAVIRUS (COVID-19), NAA TEST [139900]

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. LabCorp 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 LabCorp's test for COVID-19, including test methodology, appropriate specimen types, specimen packaging and shipping, and test result reporting.

1. Does LabCorp offer a test to detect the presence of the 2019 novel coronavirus?

A: Yes. The LabCorp 2019 Novel Coronavirus (COVID-19), NAA [139900] 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. What is the test methodology for 2019 Novel Coronavirus (COVID-19), NAA?

A: This is a qualitative test using PCR technology that was developed internally by LabCorp and is being made available in accordance with guidance issued by the FDA issued on February 29, 2020. The LabCorp assay is a multi-target PCR that provides definitive reporting for the detection of SARS-CoV-2 and does not require confirmatory testing by CDC. Per the FDA guidance, LabCorp will confirm a small number of samples with an alternate, authorized assay, such as the CDC SARS-CoV-2 EUA assay.

3. Who can order LabCorp's 2019 Novel Coronavirus (COVID-19), NAA test?

A: The test 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.

4. What are acceptable samples types for 2019 Novel Coronavirus (COVID-19), NAA?

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

5. How should samples be shipped?

A: The preferred method of shipment is frozen samples, however samples can be shipped refrigerated at 2-8°C and are stable at this temperature up to 72 hours. Specimens should be shipped overnight to the laboratory according to standard operating procedures.

6. What are the criteria for sample rejection?

A: Unacceptable specimens include those that are:

- Improperly labeled, grossly contaminated, broken or with significant leakage in transit;
- Improperly collected, ie, swabs with calcium alginate or cotton tips, swabs with wooden shafts;
- Improperly shipped, ie, shipped at room temperature or refrigerated samples that exceed the 72- hour stability;
- Collected in contact with substances inhibitory to polymerase chain reaction (PCR) technology including heparin, hemoglobin, ethanol and EDTA.

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7. How long will it take LabCorp 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 being reported to the ordering provider by telephone.
- We are also reporting test results to public health authorities as may be required
- In some cases, additional time should be allowed for additional confirmatory or additional reflex tests.

8. How will ordering physicians be notified of positive results?

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

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

A: LabCorp 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.

10. Will LabCorp send positive tests to the CDC or state health labs for confirmatory testing?

A: No. The LabCorp 2019 Novel Coronavirus (COVID-19), NAA [139900] assay is 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 LabCorp's test 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.

11. Does a negative result from LabCorp's test for COVID-19 mean that a patient is definitely not infected?

A: Not necessarily. LabCorp's COVID-19 assay 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 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 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.

12. Can I have COVID-19 testing done at a LabCorp patient service center?

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

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

A: No. Respiratory Pathogen Profile, PCR does not detect COVID-19, but it may be useful to detect other suspected respiratory tract infections, such as influenza, parainfluenza, and respiratory syncytial virus.

14. 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 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.

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