Q&A | LABCORP'S TESTING FOR COVID-19

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

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

A: Yes. LabCorp's 2019 Novel Coronavirus (COVID-19) testing [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. 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.

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

A: The COVID-19 tests performed by LabCorp are qualitative assays using PCR technology, which LabCorp played a central role in commercializing when PCR was introduced nearly 30 years ago.

4. Are you performing the Roche test for COVID-19 (cobas SARS-CoV-2)?

A: Yes. Beginning Monday, March 16, 2020, LabCorp is performing the Roche test for COVID-19.

5. What are the differences between the different versions of the COVID-19 tests offered by LabCorp?

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 LabCorp 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 LabCorp 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 LabCorp to best support the need for increased testing capacity.

7. Who can order LabCorp'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
- bronchial washings or bronchoalveolar lavage (BAL) specimens in sterile cups.

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).

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10. How should specimens be collected?

A: Detailed instructions for NP and OP specimen collection, including illustrated guides, can be found on our website, LabCorp.com/COVID-19.

11. What are the criteria for sample rejection?

A: Unacceptable specimens include those that are:

- Cotton-tip swabs in UTM/VTM;
- swabs with calcium alginate;
- swabs with wooden shafts;
- 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
- glass tubes/containers

12. How long will it take LabCorp to report results back?

A:

- It takes approximately 2-4 days from the date of pickup of a specimen for testing to the release of the test result to the health care provider.
- Test results are most typically reported electronically, which generally allows for faster delivery.
- This timeframe can vary based on demand, the length of time to transport the specimen to LabCorp's test facilities, and the prioritization of patients (as defined by healthcare authorities and the White House Coronavirus Task Force, HHS and other health authorities). LabCorp is working continuously to support the needs of healthcare workers, patients, government, clients and other organizations, and expects capacity to continue to increase.

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: 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.

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 LabCorp.

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

A: Not necessarily. LabCorp'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, 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.

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.

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