

COVID-19 Commercial Laboratory Guidance for Healthcare Providers | Updated 3/10/2020

Commercial Testing for COVID-19 Now Available

Physicians and other healthcare providers can now order a 2019 Novel Coronavirus (COVID-19) test through a commercial laboratory for patients who are ill with signs and symptoms consistent with COVID-19, but do not meet the Maricopa County Public Health testing criteria for testing at the Arizona State Public Health Laboratory (listed in table on page 4). Individuals with symptoms consistent with COVID-19 should see a healthcare provider. DO NOT go to LabCorp or Sonora Quest Laboratory.

The test detects the presence of the virus that causes COVID-19 and is for use with patients who have signs and symptoms consistent with COVID-19. For additional information on COVID-19, please refer to CDC website, which is <u>available here</u>.

Starting Monday, 3/9/2020, commercial laboratory testing is available at:

LabCorp
<u>https://www.labcorp.com/information-labcorp-about-coronavirus-disease-2019-covid-19</u>

Starting Wednesday, 3/11/2020, commercial laboratory testing is available at:

Sonora Quest Laboratories
<u>https://www.sonoraquest.com/our-response-to-coronavirus-disease-2019-covid-19/</u>

Clinicians & laboratorians <u>SHOULD NOT</u> call Public Health to coordinate Commercial Testing for COVID-19

Patients: Please do <u>not</u> go to LabCorp or Sonora Quest Laboratories for COVID-19 testing. Patients cannot order this test directly. Contact your healthcare provider for information about testing.

Infection Control Precautions

What precautions should healthcare providers use with persons under investigation for COVID-19?

When in a room with a patient with, or suspected to have, COVID-19, and <u>NO aerosol-generating</u> <u>procedures are being performed</u> (e.g., suctioning, intubation, CPAP/BiPAP), all healthcare personnel should wear:

- Surgical (medical) mask
- Gown
- Gloves
- Eye protection (e.g., goggles or face shield)

Additional infection control for healthcare providers available here: <u>https://www.maricopa.gov/5491/Healthcare-Provider-Guidance</u>

Do patients need to stay in standard, contact precautions with eye protection while waiting for test results?

Yes, individuals with symptoms need to remain in these precautions as long as they have symptoms. Discharged patients should be instructed to remain home while ill.



Specimen Collection by Healthcare Provider – NO COLLECTION AT COMMERCIAL LABORATORY

All specimens must be obtained by a clinician.

Commercial labs do not currently collect specimens for COVID-19 testing. Patients for whom testing has been ordered should not be sent to a commercial laboratory location to have a specimen collected.

What specimens will be acceptable for testing?

- Preferred samples:
 - Oropharyngeal (OP) swab in viral transport medium (VTM)
 - Nasopharyngeal (NP) swab in viral transport medium (VTM)
- Acceptable samples:
 - 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

How do I collect specimens?

- Use only synthetic fiber swabs with plastic shafts. <u>Do not use</u> calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 L of viral transport media. NP and OP specimens may be kept in separate vials or combined at collection into a single vial.
- **Nasopharyngeal (NP) swab:** Insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions.
- Oropharyngeal (OP) swab (e.g., throat swab): Swab the posterior pharynx, avoiding the tongue.
- Nasopharyngeal wash / aspirate or nasal aspirate: Collect 2-3 mL into a sterile, leak-proof, screwcap sputum collection cup or sterile dry container.

Specimen Labeling, Storage & Shipping

Labeling

Label each specimen container with the patient's ID number (e.g., medical record number), unique specimen ID (e.g., laboratory requisition number), specimen type (e.g., OP) and the date the sample was collected.

Storage & Shipping

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.



Send-outs for Healthcare Providers Only – Patients Cannot Directly Order Tests

All specimens going to a commercial laboratory need to be coordinated by the healthcare provider. Healthcare providers should work within their own healthcare facility to coordinate laboratory send-outs. **Public Health will not be involved in coordinating the send-out.**

How may I order a commercial laboratory test?

- LabCorp
 - o Test Code: 139900 <u>https://www.labcorp.com/tests/139900/2019-novel-coronavirus-covid-19-naa</u>
- Sonora Quest Laboratory
 - Test Code: Not available, as of 3/10/2020; please check Sonora Quest Laboratory website

Estimated Turnaround Time

What is the turnaround time for LabCorp and Sonora Quest Laboratories COVID-19 testing?

LabCorp and Sonora Quest Laboratories are reporting a 3-4 day turnaround time.

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

The labs will be operating 7 days a week.

Laboratory Results

Will commercial lab testing be considered confirmatory or presumptive?

 Right now, commercial testing will be considered presumptive positive, and patients should be managed as if they are positive. The test will have to be confirmed by the Arizona State Public Health Laboratory.

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

- Not necessarily. LabCorp's COVID-19 assay detects the virus directly, within the established limits of detection for which is was validated. However, a negative result does not definitely rule out infection. As with any test, the accuracy relies on many factors:
 - The test 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 an individual was exposed prior to the collection of the specimen can also influence whether the test will detect the virus
 - o Individual response to the virus can differ
 - Whether the specimen we receive was collected properly, sent promptly, and package correctly

Guidance for Laboratorians

Please see the CDC website for interim guidance and resources for laboratory professions working with specimens from persons under investigation for COVID-19: <u>https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html</u>



Additional Resources from LabCorp

- Q&A | LabCorp 2019 Novel Coronavirus (COVID-19), NAA Test [139900] <u>https://www.labcorp.com/assets-media/2330</u>
- Specimen Collection and Shipping Instructions https://www.labcorp.com/assets-media/2331
- Sonora Quest Laboratory Website

https://www.sonoraquest.com/our-response-to-coronavirus-disease-2019-covid-19/

Public Health COVID-19 Testing Criteria at Arizona State Public Health Laboratory

Only patients who meet the Persons Under Investigation (PUI) criteria can be tested at the state public health laboratory for COVID-19. These requests for testing must be approved by the local health department.

Criteria to Guide Evaluation of Persons Under Investigation (PUI)

Clinical Features	Plus	Epidemiologic Risk
Fever1 OR signs/symptoms of lower respiratory illness (e.g., cough or shortness of breath) NOT requiring hospitalization	AND	Any person, including health care workers ₂ , who has had close contact ₃ with a laboratory-confirmed ₄ COVID-19 patient within 14 days of symptom onset
Fever ₁ OR signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) NOT requiring hospitalization in a person with a high-risk occupation* OR who lives in a congregate setting [†]	AND	A history of travel from affected geographic areas ₅ within 14 days of symptom onset
Fever ₁ AND signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization	AND	A history of travel from affected geographic areas ₅ within 14 days of symptom onset
Fever ₁ AND severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization, radiographic confirmation of bilateral pulmonary infiltrates, & without alternative explanatory diagnosis (negative influenza testing & respiratory viral panel) _{6,7}	AND	No source of exposure has been identified
¹ Fever may be subjective or confirmed. ² For healthcare personnel, testing may be considered if there has been exposure to a p ³ Close contact is defined at the CDC website: <u>https://www.cdc.gov/coronavirus/2019-</u> ⁴ Documentation of laboratory-confirmation of 2019-nCoV may not be possible for trav ⁵ Countries or counties/states where sustained community transmission has been ident counties/states such as Snohomish County, WA, Solano County, CA, etc.) which can cha ⁶ Category includes single or clusters of patients with severe acute lower respiratory illr being considered	nCoV/hcp/c elers or per ified (e.g., o ange rapidly	l <u>inical-criteria.html</u> sons caring for patients in other countries. countries with CDC Level 2 or 3 Travel Health Notice and /
⁷ Also consider testing for Coccidioidomycosis and Legionella		

*Healthcare personnel, school personnel, childcare worker, jail/prison personnel, or other similar occupation

⁺Jail/prison, long-term care facility or nursing home, university, or other similar setting