COVID-19 Testing Guidance

May 5, 2020

Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing) but some people may present with other symptoms, which may include chills, myalgia, headache, sore throat, and a new loss of taste or smell. Testing should also be considered for asymptomatic persons in certain situations.

PRIORITIES FOR COVID-19 TESTING
(Nucleic Acid or Antigen)

High Priority

- Hospitalized patients **with** symptoms
- Healthcare facility workers, workers in congregate living settings, and first responders **with** symptoms
- Residents in long-term care facilities or other congregate living settings, including prisons and shelters, **with** symptoms
- Persons identified through public health cluster and selected contact investigations

Priority

- Persons who had close contact (within 6 feet for at least 10 minutes) with someone who tests positive for COVID-19, both **with** and **without** symptoms.
- Residents and staff in long-term care facilities or other congregate living settings, including prisons and shelters, as part of house-wide point prevalence studies, including those **with** and **without** symptoms.
- Persons **with** symptoms of COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea and/or sore throat.

COVID-19 testing is available at many commercial laboratories and at the New Jersey Public Health and Environmental Laboratory (PHEL). The proliferation of available tests, especially rapid tests, that can provide results within a few hours of presentation or at the point of care has the potential to significantly improve the ability to identify and manage cases. However, because of rapid emergency use authorization and in some cases lack of FDA review, care should be taken in selecting a testing platform and interpreting results.

Molecular assays that detect nucleic acid from the SARS-CoV-2 virus are considered a gold standard for the detection of SARS-CoV-2 in persons suspected of having COVID-19. There are several molecular assays that have received an EUA, including two point of care tests that can be used outside of a laboratory setting and provide results within 30 minutes. Rapid antigen tests are also acceptable for diagnosing acute illness.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

Serologies: Serological tests detect evidence of the body's immune response to an infection (antibodies), which can provide information on both current and prior infection. Current evidence indicates that COVID-19 antibodies begin to develop approximately 6 to 10 days after infection. Serology testing for COVID-19 may be used to identify people who were previously infected with COVID-19. Serology testing should not be used to diagnose current COVID-19 infection since antibody responses to infection may take days to weeks to be detectable; a negative serologic test does not rule out active infection; and a positive serologic test may reflect prior infection with a human coronavirus other than SARS-CoV-2.

Specimens: CDC recommends collecting and testing an upper respiratory specimen, with a nasopharyngeal (NP) specimen as the preferred choice for swab-based SARS-CoV-2 testing. Alternate specimen types may be available and will depend on the specific test being performed. Clinicians should contact their reference lab to find out what specimen types are acceptable and if testing supplies are available. Alternately, clinicians can order testing supplies from their contracted medical supplier.

Public Health and Environmental Laboratories (PHEL) Testing

Testing Criteria: Public health testing (PHEL) is prioritized for vulnerable populations at greatest risk for adverse outcomes, those in high-risk professions, and testing associated with public health investigations, specifically:

- Hospitalized patients with COVID-compatible illness;
- Persons with COVID-compatible illness who work, attend, or are residents of healthcare facilities (acute care, outpatient, long-term care), or other congregate settings (school or daycare facilities, homeless shelters, correctional facilities, etc.);
- Persons with COVID-compatible illness who are associated with clusters or outbreaks as identified by state/local health agencies.

Requesting Testing: For patients meeting public health testing criteria, acute care facilities requesting testing at PHEL should enter cases into CDRSS:

- Select disease subgroup 2019 NCOV;
- Enter medical facility (date of admission, if in ICU or on ventilator) and treating provider information;
- Enter signs and symptoms and complete ADDITIONAL REQUIREMENTS section;
- In the LABORATORY AND DIAGNOSTIC TEST INFORMATION section add the test "SARS CORONAVIRUS 2 RNA BY PCR" and add "NJPHEL" to the lab name;
- Include the CDRSS Case ID# as the "CDS Approval Number" on the PHEL SRD-1 form (*one SRD-1 form is required for each specimen:* https://www.nj.gov/health/forms/srd-1.pdf.
- Email the Virology group at Virology.PHEL@doh.nj.gov with the CDRSS # and the estimated delivery time of the specimens.

Providers and facilities not having access to CDRSS should contact their local health department, who should enter the case into CDRSS and issue the SRD-1 form to the provider/facility.

PHEL Testing Results: Results should be available 24-48 hours after PHEL receives the specimen(s) and are provided via fax to the submitting laboratory and reported electronically in CDRSS. If it has been > 4 days since the specimen was received at PHEL, contact the NJ Public Health and Environmental Laboratory-Virology Program at 609-530-8516 or virology.PHEL@doh.nj.gov.

Shipping: Information regarding specimen packaging, shipping, and courier instructions is available in the NJDOH PHEL COVID-19 Technical Bulletin at https://nj.gov/health/phel/documents/Bulletins/Supplemental%20Bulletin%2020.1.5%20SARS-CoV-2%20Testing%20at%20PHEL%20V5.pdf. Label the ***vial containing the specimen*** with patient's first and last name, date of birth, medical record number, date of collection, and specimen type. Incorrectly labeled samples may be denied testing. Specimens will be tested in the order they are received but those that are identified to be part of a cluster will be prioritized. If you have questions or need assistance with specimen selection, collection, packaging or shipping, contact the NJ Public Health and Environmental Laboratory Virology program at: Tel: (609)-530-8516 or email: Virology.PHEL@doh.nj.gov.

References:

New Jersey PHEL Technical Bulletin for COVID-19: https://www.nj.gov/health/phel/documents/Bulletins/Supplemental%20Bulletin%2020.1.4%20SARS-CoV-2%20Testing%20at%20PHEL.pdf

New Jersey PHEL SRD-1 Testing Request Form: https://www.nj.gov/health/forms/srd-1.pdf

CDC Interim Infection Prevention and Control Recommendations: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

CDC Evaluating and Testing PUI: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

CDC Guidelines for Clinical Specimens: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

FDA: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd