Chicago Department of Public Health

Health Alert

CDPH Chicago Department of Public Health

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Considerations for Selecting a COVID-19 Diagnostic Test

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Summary and Action Items

- Available viral tests for COVID-19 include rapid antigen tests, rapid molecular tests and RT-PCR. CDPH does not formally evaluate test performance; the FDA is the best source of information about approved tests. Antibody tests are not recommended for COVID-19 diagnosis.
- **Any positive viral test result in an individual with symptoms or confirmed exposure (i.e. a high pre-test probability) should be considered positive for public health purposes** and does not require confirmatory testing**.**
- Factors to consider when deciding which viral test to use include: the suspicion for COVID-19 based on clinical presentation and presence or absence of other conditions that may cause a similar presentation; the timing of testing in relation to symptoms (if present); risk of exposure to COVID-19; underlying risk factors that make a severe COVID-19 outcome more likely and the risk of onward transmission.
- All COVID-19 test results, including point-of-care tests, must be reported to public health by electronic laboratory reporting or CDPH's confidential Online Case Report Form: redcap.link/chicovidreport.

Background: Chicago Department of Public Health (CDPH) continues to recommend SARS-CoV-2 viral testing for anyone with possible COVID-19 symptoms and anyone with close contact to a person with COVID-19. Viral testing should also be considered for anyone with potential high-risk exposures, including those who have attended large gatherings, been in crowded spaces for 15 minutes or more, or those returning from travel to a high-incidence area. For those with confirmed or possible exposures, the optimal time for specimen collection is between 5-9 days after their last exposure, and testing does not remove the need for a 14-day complete quarantine period. We do not currently recommend antibody testing for COVID-19 diagnosis.

Authorized assays for viral testing to identify current infection include those that detect SARS-CoV-2 RNA (molecular tests) or SARS-CoV-2 antigens. The testing landscape for COVID-19 is changing rapidly. CDPH does not formally evaluate the performance of tests for SARS-CoV-2, and relies on publicly available data from FDA and CDC – a complete list of viral tests with Emergency Use Authorization (EUA) is maintained by FDA. We do not recommend the use of any test that does not have an EUA.

This guidance is intended to provide a general framework for viral test selection and result interpretation. Not all viral tests have equivalent sensitivity and specificity. There is particular variation in the sensitivity of different assays. Sensitivity is also highly dependent on the stage of the infection (higher early in infection), and negative results should always be interpreted in the context of the exposure history and clinical presentation.

Reporting to public health:

Providers and organizations performing SARS-CoV-2 testing should be aware of all reporting requirements.

- All COVID-19 tests should be reported to I-NEDSS or directly to the local health department.
- All tests (positive or negative) must be reported in aggregate to HHS (see HHS requirements).

Positive point-of-care (POC) tests that are not included in electronic lab reporting (ELR) can be reported through CDPH's online case report form: **redcap.link/chicovidreport** (Select option1: Healthcare Facility/Laboratory).

Types of tests

- Molecular tests:
    - These tests amplify and then detect specific fragments of viral RNA. Depending on the test, different sequences of RNA may be targeted and amplified.
    - Examples of this method include polymerase chain reaction (PCR), loop-mediated isothermal amplification (LAMP), and Nucleic Acid Amplification Test (NAAT). Some molecular tests may be performed at the point-of-care (POC) with rapid results.
    - Rapid POC molecular tests may have a higher rate of false negative results (lower sensitivity); if deemed necessary for clinical management or infection control purposes, negative results obtained with these rapid molecular tests may be confirmed with an alternative EUA-authorized molecular assay (such as RT-PCR).

- Antigen tests:
    - These rapid POC tests identify viral protein fragments.
    - Antigen tests perform best when used for diagnosis of COVID-19 in patients with symptoms of acute respiratory infection.
    - Antigen levels in specimens collected beyond 5-7 days of symptom onset may drop below the limit of detection.
    - Positive tests in symptomatic patients, or when there is a high pre-test probability (e.g., in outbreak settings or among close contacts of exposed cases), should be considered presumptive evidence of infection and do not require confirmatory testing.
    - Use of antigen tests for screening asymptomatic persons was not included in the FDA EUA. FDA has provided guidance, however, that such off-label use may be appropriate in some settings where access to highly sensitive tests is inadequate. If used for asymptomatic screening, SARS-CoV-2 antigen tests are expected to result in a higher proportion of false negative and false positive results. A two-test strategy may be appropriate to yield reliable results among asymptomatic individuals. If access to more sensitive molecular testing is available with rapid turnaround time, CDPH recommends preferential use of PCR in asymptomatic exposed individuals in high risk congregant settings.

Types of specimens

- For diagnostic testing, CDC currently recommends using upper respiratory specimens.
- The following are recommended: nasopharyngeal (NP), oropharyngeal (OP), nasal mid-turbinate (using a flocked tapered swab) or anterior nares/nasal swab (using a flocked or spun polyester swab). For individuals undergoing regular testing (e.g. those working in skilled nursing facilities), consider offering less invasive specimen collection methods (e.g. nasal swab).
    - Nasopharyngeal and nasal washes/aspirates and lower respiratory specimens are acceptable.
- Swabs should be placed immediately into a sterile transport tube containing 2-3mL of either viral transport medium (VTM), Amies transport medium, or sterile saline, unless using a test designed to analyze a specimen directly, (i.e., without placement in VTM), such as some POC tests.

Considerations

As with all clinical testing, no single test is perfectly sensitive or specific. When deciding the appropriate COVID-19 test to order, we recommend considering:

- Clinical presentation:
    - If you have a high clinical suspicion based on the patient's presentation but the patient initially tests negative, you may wish to request a confirmatory test with high sensitivity.
    - Alternatively, if that patient's symptoms may be explained by another condition and you have a low clinical suspicion for COVID-19, a negative SARS-CoV-2 test using any modality is sufficient evidence against current infection.

- Exposure:
    - In the context of confirmed exposure to COVID-19, you may decide a more sensitive test is beneficial even if the clinical syndrome is non-specific.

    - If an individual has a high risk of onward transmission (e.g. due to unavoidable close contact with others, particularly those at higher risk of severe COVID-19) you may decide a more sensitive test is beneficial.
- Timing of testing:
    - Tests with lower sensitivity (e.g. POC or antigen tests) are better at detecting infections when viral load is higher, e.g. within the first 5-7 days since symptom onset.
- The availability of tests and their turnaround times are also important factors to consider.

FREQUENTLY ASKED QUESTIONS (FAQs)

What if I'm worried about false negatives?
If there is strong clinical suspicion for COVID-19 (e.g. due to compatible symptoms without another clinical explanation and/or confirmed exposure), and a patient has a negative test result, the patient should be isolated and treated as a presumed positive, and repeat testing with an FDA EUA-approved molecular assay such as RT-PCR should be strongly considered. This is particularly true if the initial test was conducted using an assay with lower sensitivity, such as an antigen test and POC molecular test, especially if that test was conducted beyond 5-7 days after symptom onset.

In the context of low clinical suspicion, any negative test – including antigen tests or POC molecular tests performed within the first 5-7 days after symptom onset – may be accepted as evidence against current infection.

What if I'm worried about false positives?
The specificity is high and approximately similar across different types of testing. Given the pre-test probability with Chicago's current local disease incidence , we do not recommend routinely "confirming" a positive test result with a repeated test or another type of test, particularly if the individual is experiencing symptoms or has confirmed exposure to COVID-19. Although some "false positives" have been reported, these are difficult to definitively prove because each test has different characteristics, and there is no test with perfect sensitivity. There are many reasons why different testing modalities may provide discordant results – including the sensitivity of the different tests, the timing of specimen collection, the collection and handling of specimens and the laboratory processing. When there is uncertainty regarding how to interpret a test result in an asymptomatic person, expert clinical consultation is advised.

What tests are appropriate to use on asymptomatic people?
Among people with no symptoms, CDPH recommends testing for people with close contact to someone with COVID-19, and recommends considering testing for anyone with potential high-risk exposures, including those who have attended large gatherings, been in crowded spaces for 15 minutes or more, or those returning from travel to a high-incidence area.

Please refer to the FDA website for a current list of tests that have received EUA for use on asymptomatic individuals. Clinicians should consider the individual's pre-test probability of illness (i.e., overall prevalence of disease, exposure history). When there is uncertainty regarding how to interpret a test result in an asymptomatic person, expert clinical consultation is advised.

Where can I find more information?
- CDC: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
- FDA: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2
- APHL: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf
- IDPH: https://www.dph.illinois.gov/topics-services/diseases-and-conditions/diseases-a-z-list/coronavirus/health-care-providers
- CDPH: HAN on Considerations for COVID-19 Diagnostic Testing
  Chicago COVID Dashboard: https://www.chicago.gov/city/en/sites/covid-19/home/covid-dashboard.html

Contact coronavirus@chicago.gov for any questions.