LAHAN
Los Angeles County Health Alert Network

LAC DPH Health Advisory:

Limitations of SARS-CoV-2 Antigen Tests, Low Influenza Rates, Updates

February 3, 2021

County of Los Angeles Public Health

This message is intended for all healthcare providers in Los Angeles County. Please distribute as appropriate.

Key Messages

Limitations of SARS-CoV-2 Antigen Tests

- SARS-CoV-2 antigen tests are considerably less sensitive than initially reported. It is important that providers are aware of the limitations of these tests and that they use and interpret antigen test results based on the probability the patient has COVID-19.
- Symptomatic persons with a negative antigen test result should be instructed to isolate themselves pending confirmation by a negative RT-PCR test.
  See *Antigen Tests and Confirmatory Testing* below for more information

Low Influenza Circulation

- Respiratory virus activity is much lower than expected at this time of year for influenza and respiratory syncytial virus.
- In the setting of low influenza activity, a positive influenza test (especially antigen detection tests) is more likely to be a false positive. COVID-19 is still the leading cause of influenza-like illness in the County.
- Visit COVID Watch for information on local circulation of influenza, SARS-CoV-2, and other viral respiratory illnesses.

COVID-19 Updates

- **Timing of second COVID-19 vaccine dose:** The CDC has updated its guidance regarding the timing of the second dose. While the second dose should be administered as close to the recommended interval as possible, *if it is not feasible* to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may administered up to 6 weeks (42 days) after the first dose. CDC is not advocating for people to delay getting their second dose, but the data from clinical trials support this range. If the second dose is administered beyond these intervals, there is no need to restart the series. For more information, see CDC Clinical Considerations.
- **New web-based point of care test (POCT) result reporting*:*** Healthcare providers/clinical facilities conducting CLIA-waived testing at the point of care setting are functioning as clinical laboratories and are therefore required to report all SARS-CoV-2 test results. Providers should begin reporting all POCT results (positive and negative) via the new web-based POCT reporting portal. To begin using the portal, complete a one-time POCT clinic registration. For more information visit Provider/Clinical Facility Reporting of Point of Care Test Results.
- **Web-based Medical Provider COVID-19 Report Form**: Providers should use this web-based updated form to report laboratory confirmed (PCR/NAAT/Antigen) COVID-19 cases. Please discontinue using older outdated versions of the Medical

Provider Report Form. For more information visit *Provider Reporting*-Laboratory-confirmed COVID-19 cases.

- **Information for People with COVID-19**: New one-page handout available in 14 languages. Located in the PDF section of Isolation Instructions.

Antigen Tests and Confirmatory Testing

Currently available antigen tests have been authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) for use in *symptomatic* individuals within 5-12 days of symptom onset (the number of days varies by manufacturer). In practice, antigen tests are being used more widely for diagnostic testing and for screening purposes outside their intended use. It is important that providers are aware of the limitations of these tests and that they use and interpret antigen test results based on the probability the patient has COVID-19 (pre-test probability). A summary of when confirmatory testing of antigen results is recommended is included below.

Limitations of antigen tests

False negative results are a limitation of these tests. Recently published reports as well as local experience has found that antigen tests in symptomatic persons are less sensitive than initially reported to the FDA. In addition, these tests have a much lower sensitivity whentesting asymptomatic persons.

False positives are another limitation of antigen tests. While the specificity of antigen tests is generally high, false positive antigen tests are known to occur when the manufacturer's instructions for use are not followed correctly or if there are inadequate quality assurance procedures. False positives are also more likely to occur when testing persons with a low pre-test probability of infection (e.g., screening asymptomatic persons without risk factors in a low-prevalence setting).The FDA has issued an alert to healthcare providers regarding the potential for false-positive antigen results and steps to mitigate this risk.

Considerations for use

When used correctly, rapid antigen tests can help quickly identify patients early in the course of SARS-CoV-2 infection when viral load is highest and who pose the greatest risk of SARS-CoV-2 transmission to others. They perform best when there is a high pre-test probability of infection (e.g., symptoms consistent with COVID-19, recent exposure to a known case, and living/working in a setting where a high proportion of persons are infected).

Diagnostic testing

Antigen tests are useful as part of the evaluation of individuals with symptoms consistent with COVID-19 and/or those with a recent exposure to SARS-CoV-2. Positive antigen results are generally considered diagnostic of infection whereas negative results are presumptive.

Facilities using antigen tests for diagnostic testing should have the ability to collect same day specimens for confirmatory RT-PCR testing of negative antigen test results.

Screening

Antigen tests can have a role in screening when used to rapidly detect and monitor introduction of the virus into high risk congregate settings such as skilled nursing facilities. Timely results can help inform decisions about patient management and infection control.

Providers or facilities where screening has been implemented should refer to their setting-

specific protocols and remain aware of the performance characteristics of these tests. Results should be interpreted in the context of symptomatology, risk of exposure to SARS-CoV-2, and prevalence of COVID-19 in the setting.

Antigen tests are not recommended for screening in the general population in the absence of a recent known exposure.

Confirmatory testing
Due to the possibility of both false-negative and false-positive antigen test results, general confirmatory testing recommendations are outlined below. Clinical judgement should be used when deciding whether confirmatory RT-PCR testing should be performed. See Provider Testing FAQs; *What if I am concerned about an antigen result being a false positive* and *What if I am concerned about a result being a false negative* for more detailed information.

Note: Skilled nursing facilities and other congregate settings using antigen tests should follow their setting specific guidelines.

If indicated, confirmatory testing should be done using RT-PCR on a specimen collected as soon as possible after the antigen test and not longer than 48 hours after the initial specimen collection. Tests performed >2 days apart should be considered separate results and discordant results may be due to changes in viral dynamics.

Person with symptoms consistent with COVID-19

- If Positive – Confirmatory testing is not recommended. The patient must isolate and their close contacts must quarantine.

- If Negative – Presumptive negative, confirm with a RT-PCR. The patient should isolate while awaiting the RT-PCR test result. Provide patient with *Information for Patients with Symptoms Who Have a Negative Antigen Test* available in English and Spanish.

Asymptomatic person with known exposure in the past 14 days (e.g., a close contact to a known case or living/working in an outbreak setting)

- If Positive – Confirmatory testing is generally not recommended*. The patient must isolate and their close contacts must quarantine.
  *Consider confirmatory testing if there is lower pre-test probability of infection (e.g., non-household exposure) and/or to minimize unnecessary quarantine of their close contacts.

- If Negative – Presumptive negative. Confirmatory testing may be needed if clinical judgement deems it important for patient management or infection control. The patient should continue to quarantine as instructed. If confirmatory testing is performed, a negative RT-PCR test does not release them from the required quarantine.

Asymptomatic person with no recent known exposure (e.g. screening)
Antigen tests perform poorly in asymptomatic persons with low risk of infection and are not recommended for screening the general population. If antigen tests were used for screening:

- If Positive – Confirmatory testing is recommended. The patient must be treated as a case and instructed to isolate while awaiting the RT-PCR test result.
  Note: if confirmatory testing is not performed, then the result is considered diagnostic and the patient must complete their isolation and their close contacts must quarantine.

- If Negative – Confirmatory testing is not needed. It is important that the patient understand that the test could be falsely negative. The patient should be advised to continue all physical distancing and mask requirements. See When testing asymptomatic persons without a known exposure.

Visit the LAC DPH Provider COVID-19 Testing page for more detailed discussion of COVID-19 tests including testing FAQs.

Related references

- CDC MMWRs
  - Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2 Testing at Two University Campuses — Wisconsin, September–October 2020
  - Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2 Infection at Two Community-Based Testing Sites — Pima County, Arizona, November 3–17, 2020
- CDC Interim Guidance for Antigen Testing for SARS-CoV-2

Visit the LAC DPH COVID-19 Provider Hub for up-to-date resources and guidance.

Refresh your browser to view the latest versions

This communication was sent by Sharon Balter, MD, Director, Division of Communicable Disease Control and Prevention, Los Angeles County Department of Public Health

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