



NEW YORK CITY DEPARTMENT OF  
HEALTH AND MENTAL HYGIENE  
Dave A. Chokshi, MD, MSc  
*Commissioner*

## **2020 Health Advisory #39**

### **Proper Use and Interpretation of SARS-CoV-2 Antigen Tests**

- **SARS-CoV-2 antigen tests perform best when there is a high probability the individual who will be tested is infected with the virus.**
- **Consider the pretest probability before using SARS-CoV-2 antigen tests and when interpreting results, especially in the context of increasing community transmission. Conduct confirmatory testing when someone who:**
  - **Has symptoms, tests negative.**
  - **Has no symptoms, and no known exposure in the past 14 days, tests positive.**
- **Confirmatory testing should only be done using a nucleic acid amplification (NAA)-based test performed at a clinical laboratory on a specimen collected within 48 hours of the initial specimen (or as soon thereafter as possible). Individuals should isolate while awaiting confirmatory test results.**
- **Provided that their limitations are taken into consideration, SARS-CoV-2 antigen tests can be a valuable screening tool to identify or monitor spread of the virus in congregate settings (e.g., long term care facilities, schools).**
- **Follow-up testing cannot be used to test out of isolation after an established diagnosis of COVID-19.**
- **New York State (NYS) has modified the timeframe for provider and laboratory reporting of SARS-CoV-2 and influenza test results to require reporting within 24 hours of receiving test results, instead of three hours.**

December 14, 2020

Dear Colleagues,

The NYC Health Department is receiving a growing number of SARS-CoV-2 antigen test results. A substantial proportion of individuals initially tested with an antigen test have had discordant NAA test results when re-tested within 48 hours, providing evidence of both false-positive and false-negative antigen test results. Note that if more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a NAA should be considered a separate test rather than a confirmatory test. This Health Advisory describes how pre-test probability (the probability the patient has COVID-19) should inform use and interpretation of antigen test results.

## **Increasing Use of COVID-19 Antigen Tests in Individuals Without Symptoms or Recent Exposure to SARS-CoV-2**

Antigen tests detect the presence of proteins from SARS-CoV-2, whereas rT-PCR and other NAA-based tests detect viral RNA. While rT-PCR performed in a clinical laboratory is the best available test to detect the presence or absence of SARS-CoV-2, properly used antigen tests can offer a relatively inexpensive and rapid method to inform clinical management and can have sensitivities approaching that of NAA-based tests. However, providers must be aware of the limitations of antigen tests.

Antigen tests can help 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. Antigen tests are increasingly being used as part of the evaluation of individuals with symptoms of COVID-19 or a recent exposure to SARS-CoV-2. They are also being incorporated into screening programs to rapidly detect and monitor introduction of the virus into group settings including nursing homes, assisted-living facilities, long-term care facilities, and schools.

Antigen tests that are in use have been authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) only for use in individuals with symptoms, within five to 12 days (varies by test) of symptom onset. There are limited data on the performance of these tests in children or in individuals who have no symptoms or no known recent exposure to SARS-CoV-2. With increased use of antigen tests, in particular for the screening of individuals without symptoms who are at low risk for infection, there is growing evidence of both false-negative and false-positive results.

The decision to use antigen tests and interpretation of results should be based on the individual's pre-test probability of having COVID-19, which requires consideration of symptomatology and risk of infection due to recent exposure. Recent exposure may include close contact with a person with COVID-19 in the past 14 days or residing or working in a setting with increased SARS-CoV-2 transmission or an ongoing outbreak.

Additionally, some incorrect antigen test results are attributable to user error. Tests must be performed following the manufacturer's Instructions for Use, without deviation, by well-trained personnel. Care must be taken to avoid cross-contamination during processing of the tests. Appropriate use will further reduce inaccurate test results. The authorized instructions for use for each test can be found on the FDA's [In Vitro Diagnostics EUAs](#) webpage. See FDA's list of [EUAs for antigen tests](#) for more information about the performance and use of specific authorized tests.

As a reminder, for individuals who previously tested positive for COVID-19 and remain asymptomatic after recovery, re-testing is not recommended within 90 days of the date of

symptom onset (or date of first positive test if they had no symptoms). Refer to the [Centers for Disease Control and Prevention](#) for additional guidance.

### **False-Negative Antigen Test Results**

As detailed in [HAN#37](#), false-negative antigen results are a limitation of these tests. As such, individuals with symptoms of COVID-19 (or others, as clinically indicated) who test negative on an antigen test should be re-tested within 48 hours of the initial specimen (or as soon thereafter as possible) using a NAA-based test performed in a clinical laboratory, and should isolate while awaiting confirmatory NAA test results.

### **False-Positive Antigen Test Results**

False-positive antigen results have been reported in NYC and other jurisdictions, most often among individuals with a low pretest probability (i.e., no symptoms and no known exposure). The FDA recently issued a [letter](#) warning that false-positive results can occur with antigen tests, including when users do not follow the manufacturer's instructions. False-positive results can lead to unnecessary isolation and quarantine, school closure, and other disruptions.

### **Use of SARS-CoV-2 Antigen Test for Screening in Congregate Facilities or Settings**

Despite these limitations, SARS-CoV-2 antigen tests can be a valuable screening tool to detect and monitor spread of the virus in congregate settings. Timely results can inform decisions about patient management and infection control. Providers or facilities where screening has been implemented should refer to their internal guidance 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 incidence of COVID-19 in the setting.

### **Decision-Making Around Antigen Tests and Confirmatory Testing**

Due to the possibility of both false-positive and false-negative antigen test result, confirmatory testing should be conducted as outlined below. Confirmatory testing should only be done using a NAA-based test performed at a clinical laboratory on a specimen collected within 48 hours of the initial specimen (or as soon thereafter as possible). The pretest probability is greatest for those with symptoms of COVID-19 and will increase as the incidence of infection in the community rises or in an outbreak setting. Clinical judgment should be used to determine if a positive or negative antigen result for an asymptomatic person should be followed by confirmatory NAA testing.

1. Individual has **symptoms** – An antigen test is appropriate:
  - If Positive – Confirmatory testing is not needed. The result should be considered diagnostic of COVID-19 and the individual should be isolated and their close contacts quarantined.
  - If Negative – Consider a presumptive negative and conduct confirmatory testing. Direct the individual to isolate while awaiting the NAA test result.
2. Individual has **no symptoms but had close contact to a person with COVID-19 in the preceding 14 days** – An antigen test is appropriate:
  - If Positive – Consider a presumptive positive and conduct confirmatory testing, unless pre-test probability is high such as in an outbreak setting. Direct the individual to isolate while awaiting the NAA test result. If the NAA test result is negative, they should continue to quarantine for the appropriate period of time.
  - If Negative – Confirmatory testing is not needed unless clinical judgement deems it important for patient management or infection control. The individual should continue quarantine for the appropriate period of time.
3. **Individual has no symptoms and no known exposure to a person with COVID-19 in the preceding 14 days** – A NAA-based test should be used; however, if an antigen test is performed:
  - If Positive – Consider a presumptive positive and conduct confirmatory testing, unless pre-test probability is high such as in an outbreak setting. Direct the individual to isolate while awaiting the NAA test result.
  - If Negative – Confirmatory testing is not needed, unless clinical judgement deems it important for patient management or infection control.

Refer to new guidance from the [Centers for Disease Control and Prevention](#) for additional information on the use and interpretation of SARS-CoV-2 antigen based tests.

See the NYC Health Department's [Summary of Guidance for Isolation, Quarantine, and Transmission-Based Precautions](#) for additional guidance.

### **Negative Test Results Cannot Be Used to Shorten Isolation for Persons with COVID-19**

When a laboratory diagnosis of COVID-19 has been established, the individual must complete isolation for a minimum of 10 days from symptom onset (or, if asymptomatic, from the date of their first positive test). At this time, testing cannot be used to shorten isolation for persons with COVID-19. Providers administering tests should make sure their patients understand this to discourage unnecessary testing.

This does not apply to individuals for whom additional testing by a NAA-based test is needed to rule out a possible false-positive or false-negative antigen test result as described above.

#### **Change in timeframe for required reporting of COVID-19 and influenza test results via ECLRS**

NYS requires reporting of all SARS-CoV-2 and influenza point-of-care and other test results (e.g., positive, negative, indeterminate) by clinical laboratories and licensed professionals and facilities (including urgent care centers, medical offices, hospitals, nursing homes, pharmacies, and clinics). Test results must be reported via the Electronic Clinical Laboratory Reporting System (ECLRS). [NYS Executive Order 202.72](#) changed the required reporting timeframe to **within 24 hours** of the result, instead of three hours.

As described in [HAN#37](#), if your site does not currently report via ECLRS, contact the NYC Health Department's ECLRS team ([nyceclrs@health.nyc.gov](mailto:nyceclrs@health.nyc.gov)) and the NYS ECLRS Help Desk (866-325-7743 or [ecdrs@health.ny.gov](mailto:ecdrs@health.ny.gov)) for instructions on how to initiate reporting.

The NYC Health Department will continue to review the scientific literature and evaluate data to inform and update testing guidance.

Thank you for your continued partnership in the COVID-19 response.

Sincerely,

A handwritten signature in purple ink, appearing to read 'Celia Quinn'.

Celia Quinn, MD, MPH  
Senior Science Advisor  
Bureau of Healthcare and Community Readiness  
Office of Emergency Preparedness and Response

**The NYC Health Department may change recommendations as the situation evolves.**