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From: New York State Department of Health

Interim Guidance for the *NY Forward Rapid Test Program* Use of Antigen Testing for SARS-CoV-2 to Promote Safe Economic Activity

Purpose

This Department of Health (DOH) interim guidance is intended to inform administrators who are participating in the *NY Forward Rapid Test Program* of the appropriate use and limitations of rapid antigen tests to promote enhanced economic activity during the COVID-19 public health emergency. Specifically, this guidance provides a protocol for the screening of asymptomatic consumers who have no recent known or suspected exposure to a person with a confirmed or suspected case of COVID-19, using U.S. Food and Drug Administration (FDA) authorized rapid antigen tests. (Note that previous guidance instructs persons with symptoms of COVID-19 to isolate for 10 days.) The screening is intended to help reduce the risk of COVID-19 transmission among participants who wish to engage in certain designated economic activities.

While screening will not guarantee that participants in the program will not have COVID-19 or fully eliminate COVID-19 exposures or transmission, screening can help reduce the risk of exposure and transmission. Participation in such activity also requires adherence to industry and event specific guidance on capacity limits, testing, social distance, cleaning, and other requirements.

This guidance complements existing public health precautions and infection control measures, including, but not limited to, the use of face coverings, social distancing, and hand and respiratory hygiene that should be adhered to at all times.

Background

On March 7, 2020, Governor Andrew M. Cuomo issued Executive Order 202, declaring a state disaster emergency in response to COVID-19. As community transmission of the virus occurred throughout New York, many businesses and not-for-profit organizations were put on “pause,” dramatically reducing their in-person workforce with limited exceptions for essential entities and personnel.

On April 26, 2020, Governor Cuomo announced *New York Forward*, a data-driven, science-based approach to reopen industries and businesses throughout the state. Throughout the regional reopening and subsequent cluster action initiative to address hot spots of COVID-19 cases as they emerged, New Yorkers successfully reduced and maintained the spread of COVID-19 to one of the lowest rates in the country.

On January 11, 2021, Governor Cuomo outlined a series of new actions to confront COVID-19 and support the recovery of the private sector, including the development of a rapid testing network as a tool to help businesses reopen.

On January 29, 2021, Governor Cuomo announced that catered events would be able to resume in accordance with state guidance on March 15. Such events must be approved by the local health department, will have a 50 percent capacity limit and a limit on attendance of 150 people, and all patrons must be tested prior to the event.

On February 10, 2021, Governor Cuomo announced that sports and entertainment events in major stadiums and arenas would be able to reopen with limited spectators in accordance with state guidance on February 23.

As the rate of COVID-19 transmission continues to decrease following an increase coinciding with socialization around the winter holidays, this deployment of convenient, rapid, and low-cost testing will provide New Yorkers an additional layer of protection and confidence as they resume additional economic activity.

Use and Limitations of Rapid Antigen Testing

Limited service laboratories participating in the *NY Forward Rapid Test Program* must provide consumers with NYS DOH-approved information about COVID-19 rapid testing under this program. Information may be provided via an online registration process. Limited service laboratories participating in the program must report all test results to DOH through the Electronic Clinical Laboratory Reporting System (ECLRS), which will satisfy the obligation to report to local health departments COVID-19 test results.

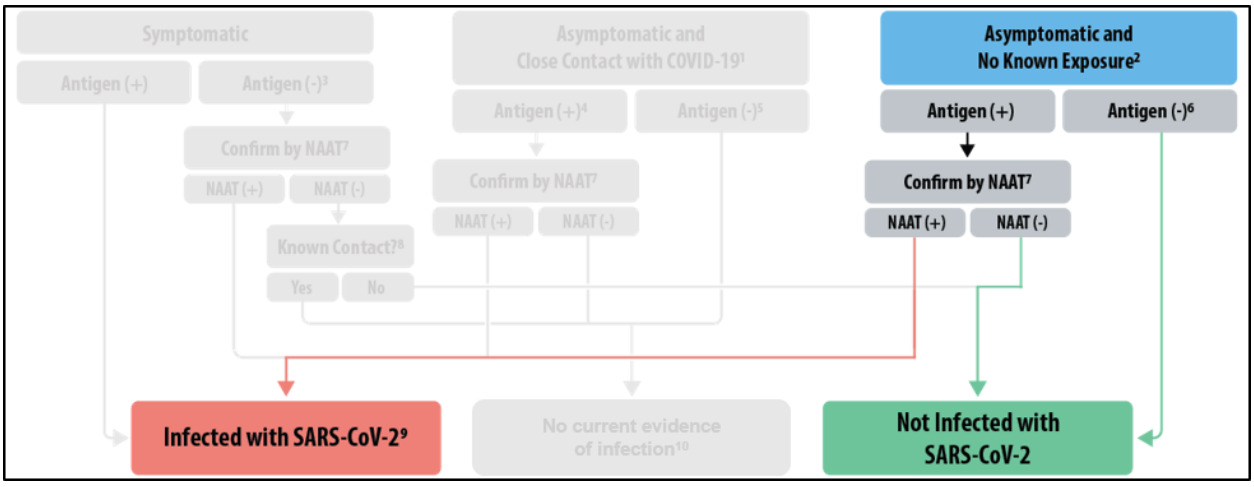
To participate in the NY Forward Rapid Test Program, individuals must have no recent known close or proximate contact to a person with a confirmed or suspected case of COVID-19 and have no symptoms of COVID-19 infection. Symptomatic individuals are not eligible to participate in the NY Forward Rapid Test Program and, as directed in previous guidance, must isolate for 10 days.

Individuals who are eligible to participate should complete the below questionnaire when they register to affirm they meet the eligibility criteria and agree as follows: (1) to allow a specimen (i.e., nasal swab) to be collected and analyzed to identify potential COVID-19 infection at a participating NY Forward Rapid Test Program test site, (2) to receive appropriate guidance about the results while at the testing site and/or when making an appointment through an online registration process, and (3) to receive their test result from the testing site in person or give permission to have the test results sent electronically.

The provider that ordered the rapid antigen test, or a representative, must call each individual that receives a positive (+) test result. The provider or a representative of the provider must clearly explain that an individual must immediately go to an appropriate location conducive to isolating for 10 days or until negative confirmatory test results from reverse transcription

polymerase chain reaction (RT-PCR) or other laboratory-based nucleic acid amplification tests (NAATs) are received, if the individual chooses to seek confirmatory testing. To be valid, specimen collection for confirmatory testing must take place within 48 hours of the rapid antigen test. If the RT-PCR confirmatory test is negative and the individual remains asymptomatic, the positive rapid antigen test will be considered a false positive, and isolation may be discontinued. This confirmatory testing sequence only applies to rapid antigen tests.

According to the Centers for Disease Control and Prevention's (CDC) "Interim Guidance for Antigen Testing for SARS-CoV-2," when testing a person who is asymptomatic and has not had known exposure to a person with COVID-19 within the last 10 days, indicating that the pretest probability of a positive antigen test is low, the healthcare provider generally can interpret a negative antigen test to indicate that the person is not infected with SARS-CoV-2. If the prevalence of SARS-CoV-2 infection is not low in the community as defined by the CDC, clinical judgment should consider whether this negative antigen test result should be followed by a confirmatory NAAT. (*See* the antigen testing algorithm when pretest probability is low, which is excerpted directly from the full antigen testing algorithm).



The CDC guidance also advises that the consumer be informed of the limitations of antigen testing including its lesser degree of sensitivity than PCR/NAATs as well as the appropriate use and interpretation of a negative (-) test result. As set forth above, negative (-) results from the antigen testing conducted through the NY Forward Rapid Test Program do not mean that an individual is not at risk for contracting or spreading COVID-19, nor does a negative result absolve an individual from meeting all *New York Forward* public health requirements, such as the use of face coverings, social distancing, hand and respiratory hygiene, and other infection control measures. A negative (-) test result obtained through the New York Forward Rapid Test Program may be used to gain access to designated economic activity for a period of 6 hours from the time of specimen collection.

Distribution of guidance to consumers will be done either at the testing site or at the time consumers schedule their appointments for rapid antigen tests via an online scheduling platform.

Consumer Screening Questionnaire

Individual consumers who are interested in participating in NY Forward Rapid Test Program must answer the following questions to determine their eligibility and must attest that they will cancel their appointments for testing and not appear at the testing site if they have any of the following symptoms on the day of their appointment or during the last 10 days:

- **Symptoms**. Are you currently experiencing, or have you recently (within the past 10 days), experienced any of the following symptoms?[1] (If answer is yes, individual cannot participate in testing program.)
    - Fever or chills
    - Cough
    - Shortness of breath or difficulty breathing
    - Fatigue
    - Muscle or body aches
    - Headache
    - New loss of taste or smell
    - Sore throat
    - Congestion or runny nose
    - Nausea or vomiting
    - Diarrhea
- **Contacts.** In the past 10 days, have you had any known close contact (or proximate contact as determined by local health authorities) with a person confirmed by a diagnostic test, or suspected based on symptoms, to have COVID-19?[2] (If answer is yes, individual cannot participate in testing program.)
- **Positive Test Result**. In the past 10 days, have you tested positive for COVID-19 through a diagnostic test? (If answer is yes, individual cannot participate in testing program.)
- **Recent Travel**. If you have traveled to a state that does not border New York within the past 10 days, did you fail to follow EITHER of the following precautions? (If answer is yes, individual cannot participate in testing program.)
    - US Travel. (1a) Quarantined for a period of 10 days upon arrival to New York OR (1b) If travel was greater than 24 hours, "tested out" of the 10-day quarantine by obtaining a diagnostic test within 72 hours prior to arrival in New York, quarantined for 3 days upon arrival, and obtained another diagnostic test on the 4th day after arrival, and received negative test results for both tests, OR if travel was less than 24 hours, "tested out" of the 10-day quarantine by obtaining a diagnostic test on the 4th day after arrival to New York and received a negative test result.
    - Travel in Another Country. (2a) Test for COVID-19 no more than 3 days prior to

[1] Note: A few of the listed symptoms may occur with pre-existing medical conditions, such as allergies or migraines, that have been diagnosed by a health care practitioner. In those cases, individuals should only answer "yes" if symptoms are new or worsening.

[2] Note: Close contact is defined by DOH as being within 6 feet of an individual for 10 minutes or more within a 24-hour period, starting from 2 days before their symptoms developed or if asymptomatic, 2 days before they were tested. Close contact does not include individuals who work in a health care setting wearing appropriate, required personal protective equipment.

flight departure, show proof of negative test result or documentation of having recovered from COVID-19 to airline before boarding flight, and obtained another test 3-5 days after travel, and quarantined for 7 days.

- **Limitations of Antigen Testing.** You acknowledge that the limitations of the rapid antigen testing have been clearly communicated to you, regarding its lesser degree of sensitivity than PCR/NAATs as well as the appropriate use and interpretation of a negative (-) test result. Negative (-) results from the antigen testing conducted through the NY Forward Rapid Test Program do not mean that an individual is not at risk for contracting or spreading COVID-19, nor does a negative result absolve an individual from meeting all *New York Forward* public health requirements, such as the use of face coverings, social distancing, hand and respiratory hygiene, and other infection control measures. A negative (-) test result obtained through the New York Forward Rapid Test Program may be used to gain access to designated economic activity for a period of 6 hours starting at the time of specimen collection.

Resources

For further information, please visit:

- DOH COVID-19 Website
  - DOH Find a Test Site Near You
- Centers for Disease Control and Prevention (CDC) COVID-19 Website
  - CDC Interim Guidance for Antigen Testing for SARS-CoV-2
- Food and Drug Administration (FDA) COVID-19 and Medical Devices
  - FDA COVID-19 Test Uses