



**SARS-CoV-2 Point of Care (POC) Antigen Tests
Frequently Asked Questions for Health Care Providers
May 13, 2021**

General Information

Q1: What is the difference between a SARS-CoV-2 antigen test and a SARS-CoV-2 PCR test?

A: Antigen tests detect a part of the virus called viral proteins, which make up the virus' structure. PCR tests, and other nucleic acid amplification tests (NAAT), are molecular tests that detect a different part of the virus called viral RNA (nucleic acid), which is the virus's genetic material.

Q2: Where can I find information on the SARS-CoV-2 antigen tests that are currently authorized for use?

A: The U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) [website](#) lists the SARS-CoV-2 antigen tests that are currently approved and available under the section entitled Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2.

Q3: Can every SARS-CoV-2 antigen test listed on the FDA EUA website be used at the point of care (POC)?

A: No. Only the SARS-CoV-2 antigen tests that have been authorized as a waived test can be used in a POC setting. In the section entitled Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 on the FDA EUA website, waived SARS-CoV-2 POC antigen tests will have a "W" under Authorized Setting(s), indicating the test is authorized as a waived test.

Q4: What specimen types are used for SARS-CoV-2 POC antigen tests?

A: The specimen type that is tested depends on the test being used. Staff performing testing need to carefully read the instructions for use (IFU) for the test being used to determine the type of specimen(s) that needs to be collected for testing. The instructions for collection of specimens vary slightly between test types so the IFU must be read carefully.

Q5: The instructions for most of the SARS-CoV-2 POC antigen tests indicate that these tests are intended to be used for the detection of SARS-CoV-2 in symptomatic individuals. Can these tests be used to test asymptomatic individuals?

A: Yes. Although there are tests that have not been authorized by the FDA for use on asymptomatic individuals, the Centers for Medicare and Medicaid Services (CMS) is temporarily exercising enforcement discretion for the duration of the COVID-19 public health emergency under the Clinical Laboratory

Improvement Amendments (CLIA) to allow the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. See CMS' [Updated CLIA SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion](#). However, it is important to remember that in most cases, the manufacturers' test performance data are only based on specimens from symptomatic individuals.

Q6: Can the SARS-CoV-2 POC antigen tests be used to test asymptomatic individuals in congregate facilities?

A: Yes. The U.S. Department of Health and Human Services (HHS) has issued [guidance](#) indicating that federal law and guidance permits the use of FDA authorized POC COVID-19 tests to screen asymptomatic individuals in congregate facilities including nursing homes, assisted-living facilities, long-term-care facilities, and other facilities where people congregate to receive care or education or to work.

Q7: Can the SARS-CoV-2 POC antigen tests be used for both diagnostic testing and screening testing?

A: Yes. SARS-CoV-2 POC antigen tests are used for diagnostic testing when performed on symptomatic individuals or asymptomatic individuals exposed to a person with COVID-19 within the last 14 days. When the same SARS-CoV-2 POC antigen test is used for screening testing, testing is performed on asymptomatic individuals even if there is no reason to suspect infection.

Q8: Is an order/prescription required to perform a SARS-CoV-2 POC antigen test?

A: Many of the SARS-CoV-2 POC antigen tests authorized by the FDA require an order by a qualified health care provider such as a medical doctor, doctor of osteopathy, dentist, nurse practitioner, certified nurse midwife or physician's assistant; and Executive Order [202.92](#) allows a licensed pharmacist to order COVID-19 tests. The FDA has authorized several SARS-CoV-2 antigen tests for non-prescription use including SARS-CoV-2 POC antigen tests that can be used at home. Therefore, it is important to carefully evaluate the test IFU to determine if a prescription is required. Additional information can be found [here](#).

Obtaining Approval to Use SARS-CoV-2 Antigen Tests

Q9: Our facility is not a laboratory, but the IFU for the waived SARS-CoV-2 POC antigen test states that testing is limited to laboratories certified under CLIA, 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests. Do we still need to be approved to perform testing using a waived SARS-CoV-2 POC antigen test?

A: Yes. Any facility performing testing using a SARS-CoV-2 POC antigen test is considered to be a laboratory and therefore must be approved by the New York State Department of Health (Department). This includes, but is not limited to,

nursing homes, adult care facilities, home health and hospice agencies, urgent care centers, physician offices, dentist offices, employers, K-12 schools, universities, pharmacies, and entertainment venues. In most cases, a facility will need to be registered by the Department as a Limited Service Laboratory (LSL). Facilities that only perform testing on their own patients may qualify for certification as a physician office laboratory (POL).

Q10: If the FDA has designated a SARS-CoV-2 POC antigen tests as waived, what type of approval is needed from the Department to perform testing using SARS-CoV-2 POC antigen tests?

A: In most cases, a facility that will only be performing waived testing using one of the SARS-CoV-2 POC antigen tests will need to be registered as an LSL or a POL. At the Federal level, issuance of a CLIA certificate of waiver provides a facility the authority to perform waived testing. An LSL registration issued by the Department is equivalent to a CLIA certificate of waiver and will allow you to perform waived testing. Please refer to question 3 above.

Q11: Who approves an LSL registration?

A: LSL registrations are issued by the Department's Wadsworth Center Clinical Laboratory Evaluation Program (CLEP).

Q12: Our facility does not have an LSL registration. How do we become approved?

A: Information on obtaining an LSL registration can be found on the Wadsworth Center CLEP [website](#). Click on "COVID-19 Response for Limited Service Laboratory Registration Requests and Additions" and then click on the link for the Registration Application.

Q13: Does an LSL need to have a laboratory director?

A: Yes. All LSLs must have a laboratory director responsible for the testing performed. New York State (NYS) licensed medical doctors, doctors of osteopathy, dentists, nurse practitioners, certified nurse midwives or physician's assistants can act as laboratory director at laboratories performing waived testing. In addition, executive order [202.92](#) allows a licensed pharmacist to direct an LSL.

Q14: Our facility already has an LSL registration, but it does not include approval to use a SARS-CoV-2 POC antigen test. Do I need to add the SARS-CoV-2 POC antigen tests to our current approval?

A: Yes. A facility with an LSL will need to add the test to their approval. Information on adding a test to an LSL registration can be found on the

Wadsworth Center CLEP [website](#). Click on “COVID-19 Response for Limited Service Laboratory Registration Requests and Additions” and then click on the link for “Add and/or Delete Test Procedures Form.” Fill out the form and follow the submission instructions.

Q15: If our facility already has an LSL registration and is approved to use a specific SARS-CoV-2 POC antigen test and we want to use another type of SARS-CoV-2 POC antigen test, do we need to submit any documentation?

A: No. Please refer to question 3 above.

Q16: If we have questions about obtaining or updating LSL registrations, who do we contact?

A: If you have any questions on how to add a test to an existing approval or on how to become approved, please contact clepltd@health.ny.gov.

Q17: For waived tests, can any facility with a NYS CLEP permit for high complexity testing perform the test without applying for expansion of permitted categories?

A: No. Laboratories holding permits for high complexity testing need to hold approval for Virology testing in order to perform SARS-CoV-2 POC antigen testing. If you have any questions, contact CLEP@health.ny.gov.

Q18: I am a provider that is designated by the Department’s Physician Office Laboratory Evaluation Program (POLEP) as a POL and hold an approval to perform testing in NYS. Can our laboratory perform SARS-CoV-2 antigen testing?

A: A POL will need to ensure that their current approval includes SARS-CoV-2 antigen testing. Adding tests requires submission of a [CMS-116 form](#). Under Section I, General Information, check the box for “Other Changes” and indicate the test being added. Under Section IV, Waived Testing, specify the manufacturer and test name. For additional information contact POLEP at CLIA@health.ny.gov.

Q19: Are there requirements for who can collect specimens?

A: Yes. On March 15, 2020, a [health advisory](#) was issued regarding specimen collection by individuals who do not hold a healthcare-related professional license from the New York State Education Department. Briefly, the advisory indicates that specimen collection by unlicensed individuals should occur only under the direction of a licensed healthcare professional who is authorized to order a COVID-19 test and who approves the training of staff to collect specimens for COVID-19 testing.

Q20: Are there licensure requirements for who can perform testing using a waived SARS-CoV-2 POC test?

A: No. Staff performing testing do not need to be licensed healthcare professionals. Staff performing the testing on specimens only need to receive training on how to perform the tests. Training should be provided by a qualified person (e.g., experienced co-worker, facility expert, or outside consultant) with knowledge of how to properly perform the test and the ability to evaluate the effectiveness of the training (e.g., does staff understand how to perform the test and are they performing the test correctly).

Reporting of Test Results

Q21: If our facility is performing testing with a SARS-CoV-2 POC antigen test, do we need to report test results to NYS?

A: Yes. All facilities who are performing SARS-CoV-2 POC antigen testing are required to report test results to the Commissioner of Health through the Electronic Clinical Laboratory Reporting System (ECLRS).

Q22: What information needs to be reported?

A: All results, including positive, negative, and indeterminate results need to be reported. In addition, facilities performing SARS-CoV-2 antigen testing are required to report:

- test type
- test result including positive, negative and indeterminate results
- test result date
- accession number
- patient age
- patient race
- patient ethnicity
- patient sex
- patient name
- patient's complete phone number
- patient date of birth
- full patient address where currently residing
- county
- ordering provider name
- ordering provider address with zip
- ordering provider phone number
- performing facility name and CLIA number
- performing facility zip code (full address)
- specimen source
- date specimen collected
- patient's occupation
- patient's employer name

- patient's work address
- patient's employer phone number
- whether the person being tested attends, works or volunteers in a school and if so, the name and location of the school. This includes elementary, secondary and post-secondary/higher education. For minors, the detailed information can be entered in the occupation and employment fields.

Q23: How often does this information need to be reported?

A: In accordance with Executive Order [202.72](#), information needs to be reported within 24 hours through ECLRS.

Q24: How are test results reported?

A: Results can be reported to ECLRS by file upload or by manual entry into ECLRS. Please contact the ECLRS Help Desk at (866) 325-7743 or eclrs@health.ny.gov with any technical questions.

Considerations When Using SARS-CoV-2 Antigen Tests

Q25: What factors need to be considered when evaluating the clinical performance of a SARS-CoV-2 POC antigen test?

A: When using a SARS-CoV-2 POC antigen test, it is important to consider the sensitivity and specificity of the test, the prevalence of the virus in the community and the pretest probability.

- The **sensitivity** of a clinical test refers to the **ability of the test to correctly identify those patients with the disease**. This is also described in terms of the positive percent agreement (% PPA) of a test. The sensitivity of SARS-CoV-2 POC antigen tests are generally lower than SARS-CoV-2 NAAT and range from 84.0%-97.6%. In general, more virus needs to be present in an individual to be detected by the SARS-CoV-2 POC antigen tests when compared to NAAT which may result in a negative SARS-CoV-2 POC antigen test and a positive SARS-CoV-2 NAAT (i.e., a false negative antigen test result).
- The **specificity** of a clinical test refers to the **ability of the test to correctly identify those patients without the disease**. This is also described in terms of the negative percent agreement (% NPA) of a test. The specificity of SARS-CoV-2 antigen tests are generally as high as the SARS-CoV-2 molecular tests. However, false positive SARS-CoV-2 antigen test results can occur, especially when the prevalence of the virus is low.
- **Prevalence** refers to the **number of cases existing in a population at a specified point in time**. The Centers for Disease Control and Prevention (CDC) considers low COVID-19 prevalence to be when NAAT positivity over the last 14 days is less than 5% or when there are fewer than 20 new cases of COVID-19 per 100,000 persons within the last 14 days.
- **Pretest probability** is the **probability that a patient has an infection before the test result is known**. Pretest probability is based on the

prevalence of the disease and the history and clinical presentation of the patient. For COVID-19, symptomatic individuals are considered to have a high pretest probability, asymptomatic individuals exposed to a person with COVID-19 within the last 14 days are considered to have a moderate pretest probability, and asymptomatic individuals with no known exposure are considered to have a low pretest probability.

Q26: Considering that SARS-CoV-2 POC antigen tests may result in false positive and false negative test results, is there a testing algorithm that can be used to determine steps that need to be taken if a symptomatic or asymptomatic individual tests positive or negative?

A: Yes. Testing algorithms and guidance have been developed by the CDC that describe use of SARS-CoV-2 POC antigen tests when testing symptomatic individuals, asymptomatic individuals exposed to a person with COVID-19 within the last 14 days, and asymptomatic individuals with no known exposure. See the CDC's [Interim Guidance for Antigen Testing for SARS-CoV-2](#). Please note that there are specific testing algorithms for long term care facilities (see below).

Q27: If a **symptomatic** individual (high pretest probability) tests **positive** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: The individual is considered to be infected with SARS-CoV-2. A positive result in this situation does not require confirmation. The result should be reported to ECLRS, and the appropriate infection control measures (e.g. isolation, contact tracing) must be taken. See [figure 2](#) in the CDC testing algorithm.

Q28: If a **symptomatic** individual (high pretest probability) tests **negative** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: A negative result on a symptomatic individual could potentially be a false negative result. The negative result should be treated as presumptive negative and confirmatory testing should be performed within 48 hours using a NAAT. See [figure 2](#) in the CDC testing algorithm. Testing for other respiratory pathogens should also be considered. The individual should quarantine until the results of the NAAT test are available.

- If the confirmatory NAAT test is positive, the individual is considered to be infected with SARS-CoV-2. Isolation must be continued, and contact tracing initiated.
- If the confirmatory NAAT is negative and the individual was exposed to a person with COVID-19 within the last 14 days, then there is no current evidence of infection. However, quarantine must be continued for individuals who are not fully vaccinated because of the exposure, as virus levels may have been below the level of detection at the time of specimen collection. Individuals who are fully vaccinated and symptomatic after an exposure but have a negative NAAT typically are not required to quarantine; such individuals residing in congregate settings should consult quarantine guidance for that setting.

- If the confirmatory NAAT is negative and the individual was not exposed to a person with COVID-19 within the last 14 days, the individual is not considered to be infected with SARS-CoV-2 and quarantine can be discontinued.

Regardless of the results of the NAAT, both the SARS-CoV-2 POC antigen test result and the NAAT result must be reported to ECLRS.

Q29: If an **asymptomatic** individual **exposed** to a person with COVID-19 within the last 14 days (moderate pretest probability) tests **positive** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: The positive result should be treated as presumptive positive and confirmatory testing should be performed within 48 hours using a NAAT. See [figure 3](#) in the CDC testing algorithm. The individual should quarantine until the results of the NAAT test are available.

- If the confirmatory NAAT test is positive, the individual is considered to be infected with SARS-CoV-2. Isolation must be continued, and contact tracing initiated.
- If the confirmatory NAAT is negative, then there is no current evidence of infection. However, quarantine must be continued because of the exposure, as virus levels may have been below the level of detection at the time of specimen collection.

Regardless of the results of the NAAT, both the POC antigen test result and the NAAT result must be reported to ECLRS.

Q30: If an **asymptomatic** individual **exposed** to a person with COVID-19 within the last 14 days (moderate pretest probability) tests **negative** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: The negative result indicates that there is no current evidence of infection. However, quarantine must be continued for individuals who are not fully vaccinated because of the exposure, as virus levels may have been below the level of detection at the time of specimen collection. See [figure 3](#) in the CDC testing algorithm. Individuals who are fully vaccinated and asymptomatic after an exposure typically are not required to quarantine; such individuals residing in congregate settings should consult quarantine guidance for that setting. The result must be reported to ECLRS.

Q31: If an **asymptomatic** individual with **no known exposure** to COVID-19 (low pretest probability) tests **positive** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: The positive result should be treated as presumptive positive and confirmatory testing be performed within 48 hours using a NAAT. See [figure 4](#) in the CDC testing algorithm. The individual should quarantine until the results of the NAAT are available.

- If the confirmatory NAAT test is positive, the individual is considered to be infected with SARS-CoV-2. Isolation and contact tracing must be initiated.
- If the confirmatory NAAT is negative, the individual is not considered to be infected with SARS-CoV-2.

Regardless of the results of the NAAT, both the POC antigen test result and the NAAT result must be reported to ECLRS.

Q32: If an **asymptomatic** individual with **no known exposure** to COVID-19 (low pretest probability) tests **negative** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: The individual is not considered to be infected with SARS-CoV-2. See [figure 4](#) in the CDC testing algorithm. However, providers should be aware that for the majority of SARS-CoV-2 POC antigen tests, there is limited data on the performance of these tests on asymptomatic individuals with no known exposure. Because of the lower sensitivity of SARS-CoV-2 antigen tests, there is always a possibility that a negative SARS-CoV-2 antigen test result on an asymptomatic individual with no known exposure could be a false negative result.

Q33: Are there other factors that can impact the performance of SARS-CoV-2 POC antigen tests?

A: Yes. If the test components are not stored or performed at the correct temperatures, results can be impacted. Improper specimen collection, reading a result in an inappropriate time frame and not performing proper decontamination of the testing area can also impact test results. It is extremely important to follow the manufacturer instructions when testing. For additional information see the [FDA's alert](#) to clinical laboratory staff and health care providers.

Information for Nursing Homes and Adult Care Facilities

Q34: CMS issued revised regulations on August 25, 2020 that establish [Long-Term Care \(LTC\) Facility Testing Requirements for Staff and Residents](#) and CMS presented information describing these new requirements. Are NYS nursing homes required to follow CMS testing requirements?

A: Yes. NYS nursing homes are required to follow these regulations and any additional requirements issued by the State in guidance, directives or Executive Orders.

Q35: Can a nursing home or adult care facility use SARS-CoV-2 POC antigen tests to perform required testing of staff and residents?

A: Yes. On August 26, 2020, CMS published [CMS Memo QSO-20-38-NH](#) that states that facilities can meet testing requirements through the use of rapid POC testing devices or through an arrangement with an offsite laboratory.

Q36: Are NYS nursing homes and adult care facilities using SARS-CoV-2 POC antigen tests required to report test results to NYS?

A: Yes. Nursing homes and adult care facilities must report test results to ECLRS or to the CDC National Healthcare Safety Network (NHSN). If test results are reported through NHSN, a facility does not need to report through ECLRS, provided the Department can verify receipt of the records from NHSN.

Q37: What CDC testing algorithms should a nursing home or adult care facility use when performing SARS-CoV-2 POC antigen testing on staff and residents?

A: The CDC has specific guidance for [SARS-CoV-2 Antigen Testing in Long Term Care Facilities](#) that describes actions that need to be taken when a nursing home or adult care facility has a positive or negative SARS-CoV-2 POC antigen test result.

Q38: Are New York State nursing homes required to follow the CDC's [SARS-CoV-2 Antigen Testing in Long Term Care Facilities](#) guidance?

A: Yes.

Q39: If a **symptomatic** resident or staff member tests **positive** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: The individual is considered to be infected with SARS-CoV-2. A positive result in this situation does not require confirmation with a NAAT. The result should be reported, and the appropriate actions (isolation of the resident, exclusion of staff from work, contact tracing, outbreak response initiated in a facility without a current outbreak) must be taken.

Q40: If a **symptomatic** resident or staff member tests **negative** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: A negative result on a symptomatic resident or staff member could potentially be a false negative result. The negative result should be treated as presumptive negative and confirmatory testing should be performed within 48 hours using a NAAT. Testing for other respiratory pathogens should also be considered. While waiting for the results from the NAAT, residents should be isolated, and staff excluded from work.

- If the confirmatory NAAT test is positive, appropriate infection control measures (isolation of the resident, exclusion of staff from work (furlough), contact tracing, outbreak response initiated in a facility without a current outbreak) must be taken.
- If the confirmatory NAAT is negative and there is an outbreak in the facility or there has been a known exposure to a person with COVID-19 within the last 14 days, continue testing the staff and residents as required. If the tested resident or staff member had a known exposure to a person with COVID-19 within the last 14 days, quarantine must be continued.

- If the confirmatory NAAT is negative and there is no outbreak in the facility or there has not been a known exposure to a person with COVID-19 within the last 14 days, residents can return to a regular room and staff are excluded from work until they meet criteria for return to work established by the facility.

See additional details in the [CDC's SARS-CoV-2 Antigen Testing in Long Term Care Facilities guidance](#). Regardless of the results of the NAAT, both the POC antigen test result and the NAAT result must be reported.

Q41: If an **asymptomatic** resident or staff member tests **positive** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A: The positive result should be treated as presumptive positive and confirmatory testing performed within 48 hours using a NAAT. Residents should be isolated, and staff excluded from work (furloughed). Residents **should not be placed** into the COVID-19-positive unit (cohort) pending the confirmatory NAAT.

- If the confirmatory NAAT test is positive, the individual is infected with SARS-CoV-2. The appropriate infection control measures (isolation of the resident in a COVID-19-positive unit (cohort), exclusion of staff from work, contact tracing, outbreak response initiated in a facility without a current outbreak) must be taken.
- If the confirmatory NAAT test is negative and there is an outbreak in the facility or there has been a known exposure to a person with COVID-19 within the last 14 days, continue testing the staff and residents as required. If the tested resident or staff member had a known exposure to a person with COVID-19 within the last 14 days, quarantine must be continued.
- If the confirmatory NAAT is negative and there is no outbreak in the facility or there has not been a known exposure to a person with COVID-19 within the last 14 days, residents can return to a regular room and staff can return to work. Continue testing staff and residents as required.

See additional details in the [CDC's SARS-CoV-2 Antigen Testing in Long Term Care Facilities guidance](#). Regardless of the results of the NAAT, both the POC antigen test result and the NAAT result must be reported.

Q42: If an **asymptomatic** resident or staff member tests **negative** with a SARS-CoV-2 POC antigen test, what actions need to be taken?

A:

- If the SARS-CoV-2 POC antigen test is negative and there is an outbreak in the facility or there has been a known exposure to a person with COVID-19 within the last 14 days, continue testing the staff and residents as required. If the tested resident or staff member had a known exposure

to a person with COVID-19 within the last 14 days, quarantine must be continued.

- If the SARS-CoV-2 POC antigen test is negative and there is no outbreak in the facility or there has not been a known exposure to a person with COVID-19 within the last 14 days, residents be in their regular room and staff can continue to work. Continue testing staff and residents as required.

See additional details in the [CDC's SARS-CoV-2 Antigen Testing in Long Term Care Facilities guidance](#). Regardless of the results of the NAAT, both the POC antigen test result and the NAAT result must be reported.

Q43: Can SARS-CoV-2 POC antigen tests be used to test nursing home residents' visitors?

A: CMS has indicated that nursing homes may use SARS-CoV-2 POC antigen tests to test residents' visitors to help facilitate visitation while also preventing the spread of COVID-19. Facilities should prioritize resident and staff testing and have adequate testing supplies to meet required staff and resident testing, before testing residents' visitors. If a nursing home will be testing visitors, the facility will need to meet all NYS requirements for testing. This includes but is not limited to having the test ordered by an authorized ordering source and meeting all requirements for testing and reporting of results.

Q44: We are currently receiving free SARS-CoV-2 POC antigen tests. Who is providing these tests?

A: Initially, HHS distributed several types of SARS-CoV-2 POC antigen tests to qualified nursing homes including the Abbott BinaxNOW COVID-19 Ag Card (Abbott BinaxNOW), the Becton Dickinson (BD) Veritor™ System, and the Quidel Sofia SARS Antigen IFA. HHS is currently distributing the Abbott BinaxNOW to nursing homes and some adult care facilities. NYS is also distributing the Abbott BinaxNOW tests to nursing homes.

Q45: Which nursing homes and adult care facilities are receiving free Abbott BinaxNOW tests from HHS?

A: The HHS Abbott BinaxNOW test allocations are based on a combination of federal COVID-19 testing guidelines, the location of the facility, and current, regional epidemiological data. It is anticipated that nursing homes and adult care facilities that are currently receiving these tests will continue to be sent tests if a facility continues to meet the criteria needed for distribution.

Q46: Are nursing homes and adult care facilities required to receive Abbott BinaxNOW tests from HHS?

A: No. If such tests are not being used, the facility may choose to opt out of the distribution of Abbott BinaxNOW tests by contacting Abbott at ARDxUSGovernmentSupport@abbott.com.

Q47: Which facilities are receiving free Abbott BinaxNOW tests from NYS?

A: NYS is currently distributing Abbott BinaxNOW tests to nursing homes located in NYS. NYS is not currently distributing these tests to adult care facilities.

Q48: How does NYS calculate the number of Abbott BinaxNOW tests that are sent to nursing homes for staff testing?

A: Nursing homes are currently required to test staff twice a week. The Department is providing Abbott BinaxNOW tests so they can be used to perform one of the twice-weekly tests. Staff numbers reported to the Department by nursing homes are used to calculate the number of tests provided and needed to perform a second weekly test of all staff. Tests are allocated monthly.

Q49: How does NYS calculate the number of Abbott BinaxNOW tests that are sent to nursing homes for visitor testing?

A: The number of tests provided for visitor testing is based on numbers reported to the Department by nursing homes. Tests for visitor testing are allocated monthly.

Q50: Will the Abbott BinaxNOW tests from NYS for staff and visitor testing be shipped together?

A: Yes.

Q51: How does a nursing home inform NYS that they do not want to receive Abbott BinaxNOW tests?

A: Please send an email to Covid19rapidtest@health.ny.gov and indicate that you do not want to receive Abbott BinaxNOW tests. Please include "nursing home" in the email subject line.

Q52: If a nursing home received Abbott BinaxNOW tests from NYS and does not want to use them, can they be returned?

A: Yes. Unused Abbott BinaxNOW tests from NYS can be returned by shipping the tests to: DHSES, HVCC: Conway Ice Arena, 80 Vandenberg Ave, Troy, NY 12180. Please do not return expired Abbott BinaxNOW tests.

Q53: If a nursing home has questions about NYS distribution of Abbott BinaxNOW tests, who should be contacted?

A: Nursing homes can send inquiries about NYS distribution of Abbott BinaxNOW tests to Covid19rapidtest@health.ny.gov. Please include “nursing home” in the email subject line.

Information for K-12 Schools

Q54: Can K-12 schools use results from SARS-CoV-2 POC antigen tests to meet testing requirements for testing of students, faculty, and staff?

A: If the SARS-CoV-2 test has EUA from the FDA, then the results from a SARS-CoV-2 POC antigen test can be used to meet testing requirements for testing of students, faculty, and staff.

Q55: Can K-12 schools perform SARS-CoV-2 POC antigen testing on-site at the school?

A: Yes. K-12 schools performing testing on-site will need to meet all requirements for SARS-CoV-2 POC antigen testing including obtaining an LSL registration, having an authorized ordering source for tests requiring a prescription, and reporting all test results to ECLRS.

Q56: Can K-12 schools request to receive free SARS-CoV-2 POC antigen tests from NYS to perform testing on their students, faculty, and staff?

A: Yes. NYS is currently providing Abbott BinaxNOW tests to schools for free while supplies are available. For additional information on how to request tests for testing of K-12 students, faculty, and staff, please contact Covid19rapidtest@health.ny.gov. Please include “K-12 school” in the email subject line.

Q57: Do K-12 schools need to be in a designated red, yellow, or orange micro-cluster zone to receive Abbott BinaxNOW tests from NYS?

A: No.

Q58: If a K-12 school is performing testing with the Abbott BinaxNOW tests and the school is not located in a designated red, yellow, or orange micro-cluster zone, do they need to report test results?

A: Yes. All test results need to be reported through the School Report card and ECLRS. Questions can be sent to schoolquestionscovid@health.ny.gov (School Report Card) and ECLRS@health.ny.gov.

Q59: Can K-12 schools use the Abbott BinaxNow antigen tests being distributed by NYS for testing of athletes?

A: No. The Abbott BinaxNow antigen tests that are being provided to K-12 schools by NYS are to test students, faculty and staff for surveillance and academic-focused activities. K-12 schools cannot use Abbott BinaxNow antigen tests supplied by NYS to test athletes to qualify them to participate in high risk sports or for testing related to other extracurricular activities. Schools may purchase tests for such purposes through Abbott, by contacting the [Sales Department](#).

Use of SARS CoV-2 POC Antigen Tests for the NY Forward Rapid Test Program

Q60: What is the NY Forward Rapid Test Program?

A: The NY Forward Rapid Test Program is a public-private partnership designed to expand rapid testing sites across NYS with the goal of building consumer confidence. This new network of testing centers will provide New Yorkers with convenient access to low-cost COVID-19 rapid tests that will help to safely accelerate reopening of the state's economy, including the cultural sector and event economy. For additional information, see the NY Forward Rapid Test Program [website](#).

Q61: Are SARS-CoV-2 POC antigen tests authorized by the FDA being used in this program?

A: Yes. SARS-CoV-2 POC antigen tests are being used for the screening of asymptomatic consumers who have no recent known or suspected close or proximate contact to a confirmed or suspected case of COVID-19, have not received a positive test result for COVID-19 in the past 10 days, and have followed the Department's COVID-19 travel advisory. Symptomatic individuals are not eligible to participate in the NY Forward Rapid Test Program.

Q62: Are the testing centers that are participating in the NY Forward Rapid Test Program required to be approved by the Department to perform SARS-CoV-2 POC antigen tests?

A: Yes. Testing centers offering this testing will need to meet all requirements for SARS-CoV-2 POC antigen testing (have an LSL registration, have an authorized ordering source for tests requiring a prescription, and report all test results to ECLRS).

Q63: Does the CDC's [Interim Guidance for Antigen Testing for SARS-CoV-2](#) apply to the NY Forward Rapid Test Program?

A: Yes. Because testing is being performed on asymptomatic individuals with no known contacts, [figure 4](#) in the CDC testing algorithm applies. For additional guidance, see the [Interim Guidance for the NY Forward Rapid Test Program Use of Antigen Testing for SARS-CoV-2 to Promote Safe Economic Activity](#).

Q64: If someone who has been tested at a NY Forward Rapid Test Program testing center that used a SARS-CoV-2 POC antigen test tests negative, how long is their SARS-CoV-2 POC antigen negative test result valid for?

A. Negative antigen test results obtained through a New York Forward Rapid Test Program site can be used to gain access to designated economic activities for a period of 6 hours starting at the time of specimen collection. However, testing all event attendees and staff for COVID-19 before allowing them to enter the venue has not been systematically studied. It is unknown if entry testing at event venues provides any additional reduction in person-to-person transmission of the virus beyond what would be expected with other preventive measures (such as social distancing, wearing cloth face coverings, hand washing, enhanced cleaning and disinfection). Additional information for consumers can be found in the [Consumer Information Sheet for the NY Forward Rapid Test Program Use of Antigen Testing for SARS-CoV-2 to Promote Safe Economic Activity](#).

Information on the Abbott BinaxNow COVID-19 Ag Card (BinaxNow) Test

Q65: Where can I find the BinaxNOW Instructions for Use?

A: The instructions for use can be found at:
<https://www.fda.gov/media/141570/download>

Q66: Is training available for the BinaxNOW?

A: Yes. Training videos, modules, helpful documents, and frequently asked questions for the BinaxNOW test can be accessed on Abbott's website. See: <https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>. The laboratory director needs to read the instructions and, ensure that staff performing testing are properly trained (have completed all training modules) and their competency has been assessed prior to commencing testing. Competency assessment is a process to make sure that staff are following the proper test procedure after initial training and should be performed at least annually and should be documented.

Q67: How do I obtain technical support for this test?

A: For questions regarding the BinaxNOW test, please call Abbott Technical Services at 1-800-257-9525 or email ts.scr@abbott.com.

Q68: What is the NAVICA app?

A: Abbott offers the NAVICA app, which is a phone app reporting system. The patient downloads the consumer app and the testing site can use the NAVICA Administrator App to pair a patient to a test card and to communicate encrypted BinaxNOW test results to participants. Note that results are reported to ECLRS separately.

Q69: Do I have to use the NAVICA app?

A: No. The results of the test can be recorded manually, and the report provided to the individual tested as per NYS requirements and your laboratory's procedures. All results must also be reported to the Department through ECLRS.

Q70: How do I store the BinaxNOW tests?

A: The kits must be stored at 2-30°C (35.6-86°F). Ensure all test components are at room temperature before use.

Q71: Do staff need to wear personal protective equipment (PPE) when collecting specimens and performing testing?

A: Yes. [Appropriate PPE](#) for your staff should be obtained and staff should be trained in the use of PPE for specimen collection and performance of the test.

Q72: What do I do with the BinaxNow card and other testing materials from the test kit after testing is performed?

A: The used card, control swabs and the reagent bottle are all considered regulated medical waste and must be placed in a red biohazard bag used for the disposal of regulated medical waste.

Q73: The bottle of extraction reagent provided is not enough to perform all 40 tests in the box. Can NYS provide more extraction reagent for the BinaxNow kits?

A: No. NYS does not have reagents available outside of the BinaxNow test kits. Each bottle is sufficient to administer the 40 tests in each kit. If you are finding that there is not enough extraction reagent to perform the 40 tests in each kit, reread the manufacturer's instructions for use and note how to hold the bottle when dispensing the extraction reagent.

Q74: Can the BinaxNow test kits be used beyond the kit's expiration date?

A: Test kits should not be used beyond the expiration date unless the manufacturer has indicated otherwise. Please note that in March 2021, Abbott announced that the expiration dates for the BinaxNow test have been extended from 6 months to 9 months. Therefore, BinaxNow tests in your possession may now have a longer than labeled product expiry date. To obtain a list of lot numbers with extended expiration dates, please contact Abbott Technical Service at (800) 257-9525 or ts.scr@abbott.com.