



**SARS-CoV-2 Point of Care (POC) Antigen Tests
Frequently Asked Questions for Health Care Providers
October 17, 2020**

General Information

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

A: SARS-CoV-2 antigen tests detect a part of the virus called viral proteins, which make up the virus's structure. SARS-CoV-2 PCR tests detect a different part of the virus called viral RNA (nucleic acid), which is the virus's genetic material.

Q2: What SARS-CoV-2 antigen tests are currently available?

A: To date, there are four SARS-CoV-2 point-of-care (POC) antigen tests that have been authorized by the U.S. Food and Drug Administration (FDA) including:

- The Abbott BinaxNOW COVID-19 Ag Card;
- the Becton Dickinson (BD) Veritor™ System;
- the LumiraDx SARS-CoV-2 Ag test; and
- the Quidel Sofia SARS Antigen IFA.

The BD Veritor™ System, LumiraDx SARS-CoV-2 Ag test and Quidel Sofia SARS Antigen IFA require an instrument to read results. The Abbott BinaxNOW COVID-19 Ag Card does not need an instrument to read results.

Q3: How can our facility obtain one of the SARS-CoV-2 POC antigen tests?

A: The U.S. Department of Health and Human Services (HHS) is currently distributing the Abbott BinaxNOW COVID-19 Ag Card, the Becton Dickinson (BD) Veritor™ System, and the Quidel Sofia SARS Antigen IFA. Nursing homes are already receiving either a Quidel Sofia 2 Instrument or BD Veritor™ Plus System. HHS is distributing the Abbott BinaxNOW COVID-19 Ag Card to nursing homes, adult care facilities, home health and hospice agencies, Historically Black Colleges and Universities (HBCUs), the Indian Health Service, and States recovering from natural disasters. HHS will also be distributing the Abbott BinaxNOW COVID-19 Ag Card directly to New York State.

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. The specimen types used are shown below. Staff performing testing need to read the instructions for use to determine the type of specimens that need to be collected for testing. The instructions for collection of specimens vary slightly between test types and should be read carefully.

- Abbott BinaxNOW COVID-19 Ag Card SARS-CoV-2: nasal swab.
- BD Veritor™ System: nasal swab.
- LumiraDx SARS-CoV-2 Ag test: nasal swab.
- Quidel Sofia SARS Antigen IFA: nasopharyngeal and nasal swabs.

Q5: The instructions for these 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 these tests have not been approved by the FDA for use on asymptomatic individuals, the Centers for Medicare and Medicaid Services (CMS) will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA and will allow the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. See <https://www.cms.gov/files/document/clia-poc-ag-test-enforcement-discretion.pdf>. However, it is important to remember that the manufacturers' test performance data are based on specimens from symptomatic individuals. At this time, data on test performance when used to test asymptomatic individuals are not available.

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

A: The U.S. Department of Health and Human Services (HHS) has indicated that federal law and guidance permits use of FDA approved POC COVID-19 tests to screen asymptomatic individuals in congregate facilities including nursing homes, assisted-living facilities, long-term-care facilities and other health or social facilities such as day programs.

See <https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf>; <https://www.cms.gov/files/document/qso-20-38-nh.pdf>.

Q7: Can the SARS-CoV-2 POC antigen tests be used to test asymptomatic individuals in congregate settings such as schools?

A: SARS-CoV-2 POC antigen tests can be used to test asymptomatic individuals associated with congregate settings such as schools, colleges, universities and other educational settings, workplaces, and other sites where people gather. See <https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf>). Schools should follow guidance for testing of individuals in congregate settings. For schools located in outbreak areas, providers should follow guidance for use of the test in a congregate settings in an areas where there is a public outbreak. For schools not located in outbreak areas, providers should follow guidance for use of the test in a congregate settings in an areas where there is not a public outbreak. Schools located in yellow zone should consult the "Interim Guidance on Mandatory COVID-19 Testing in Public and Non-Public Schools Located in Areas Designated as "Yellow Zones" Under the New York State Cluster Action Initiative" at https://coronavirus.health.ny.gov/system/files/documents/2020/10/guidance_for_school_testing_in_yellow_zone10_9_2020.pdf.

Obtaining Approval to Use SARS-CoV-2 Antigen Tests

Q8: Our facility is not a laboratory, but the instructions for the SARS-CoV-2 POC antigen tests state that testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (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 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 will need to 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, employers, K-12 schools and universities. In most cases, a facility will need to be registered as a Limited Service Laboratory (LSL) or have a contractual relationship with an LSL to perform such tests.

Q9: The FDA has designated the 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 a Limited Service Laboratory (LSL). At the Federal level, issuance of a CLIA certificate of waiver provides a facility the authority to perform waived testing. An LSL registration is equivalent to a CLIA certificate of waiver and will allow you to perform waived testing.

Q10: Who issues an LSL registration?

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

Q11: Our facility does not have an LSL registration. How do we become approved?

A: LSL registrations are issued by the Department's Wadsworth Center Clinical Laboratory Evaluation Program (CLEP). To become registered, a nursing home, adult care provider or other entity must submit a complete LSL application. LSL application materials can be found at:

<https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs>. Click on "Obtaining a Limited Service Laboratory Registration Certificate" to review additional information and to access the application materials.

Q12: Our facility already has an LSL registration. Should I 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. To add a test to your LSL registration, go to:

<https://www.wadsworth.org/regulatory/lep/limited-service-lab-certs>. Click on “Changing a Limited Service Laboratory Registration Certificate” and then choose “Add and/or Delete Test Procedures”. Fill out the form and follow the submission instructions.

Q13: 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.

Reporting of Test Results

Q14: If our facility is performing testing with a SARS-CoV-2 POC antigen test, do we need to report test results to New York State?

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). Failure to report test results can result in a civil penalty.

Q15: 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 and negative 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.

Q16: How often does this information need to be reported?

A: Information needs to be reported as required by Executive Order. Pursuant to Executive Order 202.61 information must be reported, currently defined as within 3 hours through ECLRS.

Q17: 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

Q18: Do the SARS-CoV-2 POC antigen tests perform as well as a SARS-CoV-2 PCR test?

A: The performance of a test is typically expressed in terms of sensitivity and specificity.

- The **sensitivity** of a clinical test refers to the ability of the test to correctly identify those patients with the disease. SARS-CoV-2 antigen tests are generally less sensitive than SARS-CoV-2 PCR tests. The sensitivity of SARS-CoV-2 POC antigen tests range from 84.0%-97.6%.
- The **specificity** of a clinical test refers to the ability of the test to correctly identify those patients without the disease. The specificity of SARS-CoV-2 antigen tests are generally as high as the SARS-CoV-2 PCR tests.

Q19: Does the lower sensitivity impact how SARS-CoV-2 POC antigen tests are used and the actions that need to be taken after receiving a positive or negative result?

A: Yes. SARS-CoV-2 POC antigen tests have a lower sensitivity compared to lab-based SARS-CoV-2 PCR tests resulting in a potential for a false negative result. When the pretest probability (prevalence) is high, there is an increased likelihood of false negatives. Additionally, when the pretest probability (prevalence) is low, there is an increased likelihood of false positives, at levels depending on the specificity of the test.

Q20: 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 when using a SARS-CoV-2 POC antigen test?

A: Yes. Testing algorithms have been developed describing how SARS-CoV-2 POC antigen tests can be used when testing the general public in an outbreak setting and how SARS-CoV-2 POC antigen tests can be used by nursing homes and adult care facilities to perform testing on residents and employees. These algorithms are attached to this document. The testing algorithms describes how the tests can be used for symptomatic or asymptomatic individuals, if a confirmatory lab-based SARS-CoV-2 PCR test is needed and actions to be taken if the confirmatory test is positive or negative.

Use of SARS-CoV-2 Antigen Tests During a Outbreak in a Public Setting (see attached algorithms)

Q21: If I test a ***symptomatic*** individual in an area with an outbreak using a SARS-CoV-2 POC antigen test, and the antigen test is ***positive***, does the positive result need to be confirmed?

A: No. A positive result in this situation does not require confirmation. The result must be reported to ECLRS, and the appropriate actions (e.g. isolation, staying home from school or work, contact tracing) must be taken.

Q22: If I test a ***symptomatic*** individual in an area with an outbreak using a SARS-CoV-2 POC antigen test, and the antigen test is ***negative***, does the negative result need to be confirmed?

A: Yes. Due to the lower sensitivity of the SARS-CoV-2 POC antigen tests there is an increased likelihood of false negatives. A confirmatory laboratory-based SARS-CoV-2 PCR test should immediately be performed in conjunction with testing for other respiratory pathogens. The individual should quarantine and stay home from school or work until the PCR test results are obtained.

- If the confirmatory laboratory-based PCR is positive, the individual must be put on isolation and continue to stay out of school or work. Contact tracing must be initiated.
- If the confirmatory laboratory-based PCR is negative, quarantine should be discontinued, and school or work can be resumed.

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

Q23: If I test an ***asymptomatic*** individual in an area with an outbreak using a SARS-CoV-2 POC antigen test, and the antigen test is ***positive***, does the positive result need to be confirmed?

A: No. A positive result in the setting of an outbreak or high prevalence area/group does not require confirmation. The result must be reported to ECLRS,

and the appropriate actions (e.g. isolation, staying out of school or work, and contact tracing) must be taken.

Q24: If I test an **asymptomatic** individual in an area of an outbreak using a SARS-CoV-2 POC antigen test, and the antigen test is **negative**, does the negative result need to be confirmed?

A: Due to the potential of a false negative result, confirmatory laboratory-based SARS-CoV-2 PCR test should be considered. The confirmatory PCR test should occur on the same day as the antigen test. If this is not possible, it can be performed up to 48 hours later maximum. Note that data on the performance of antigen tests on asymptomatic individuals is not yet available and the value of a confirmatory PCR test is higher in areas where the virus is prevalent. If a follow-up PCR test is performed, then the individual should be quarantined and stay out of school and work until the PCR test results are obtained.

- If the confirmatory laboratory-based PCR is positive, the individual must be put on isolation and continue to stay out of school or work. Contact tracing must be initiated.
- If the confirmatory laboratory-based PCR is negative, quarantine should be discontinued, and school or work can be resumed.

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

Use of SARS-CoV-2 Antigen Tests by Nursing Homes, Adult Care Facilities and Other Congregate Facilities and Settings

Q25: If I test a **symptomatic** individual in these facilities or settings using a SARS-CoV-2 POC antigen test, and the antigen test is **positive**, does the positive result need to be confirmed?

A: No. A positive result in this situation does not require confirmation. The result must be reported to ECLRS, and the appropriate actions (e.g. isolation, staying home from school or work, contact tracing) must be taken.

Q26: If I test a **symptomatic** individual in a facilities or settings using a SARS-CoV-2 POC antigen test, and the antigen test is **negative**, does the negative result need to be confirmed?

A: Yes. Due to the lower sensitivity of the SARS-CoV-2 POC antigen tests there is an increased likelihood of false negatives. A confirmatory laboratory-based SARS-CoV-2 PCR test should immediately be performed in conjunction with

testing for other respiratory pathogens. The individual should be quarantined and stay out of school and work until the PCR test results are obtained.

- If the confirmatory laboratory-based PCR is positive, the individual must be put on isolation and continue to stay out of school or work. Contact tracing must be initiated.
- If the confirmatory laboratory-based PCR is negative, quarantine should be discontinued, and school or work can be resumed.

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

Q27: If I test an **asymptomatic** individual in facilities or settings using a SARS-CoV-2 POC antigen test in a facility with an outbreak and the antigen test is **positive**, does the positive result need to be confirmed?

A: No. A positive result in the setting of an outbreak does not require confirmation. The result must be reported to ECLRS, and the appropriate actions (e.g. isolation, staying out of school or work, and contact tracing) must be taken.

Q28: If I test an **asymptomatic** individual in facilities or settings using a SARS-CoV-2 POC antigen test in a facility with an outbreak and the antigen test is **negative**, does the negative result need to be confirmed?

A: No. Serial testing should be continued as described by CMS. See CMS Memo QSO-20-38-NH: <https://www.cms.gov/medicareprovider-enrollment-and-liarule-ifc-cms-3401-ifc-additional-policy-and-regulatory-revisions-response-covid-19>.

Q29: If I test an **asymptomatic** individual in facilities or settings using a SARS-CoV-2 POC antigen test in a facility without an outbreak and the test is **positive**, should the positive result be confirmed?

A: Yes. Due to uncertain specificity of the SARS-CoV-2 POC antigen tests when performed on asymptomatic individuals, there might be an increased likelihood of false positives. A confirmatory laboratory-based SARS-CoV-2 PCR test should be performed within 48 hours and preferably the same day as the antigen test. The individual must be quarantined until the PCR test results are obtained.

- If the confirmatory laboratory-based PCR is positive, the individual must be isolated, and the facility must initiate an outbreak response.
- If the confirmatory laboratory-based PCR is negative, quarantine should be discontinued unless the patient has become symptomatic.
- If the PCR test result is not available within 3-days after performing the SARS-CoV-2 POC antigen test, the facility should proceed with other

appropriate actions such as isolating the individual and initiating outbreak response.

As more is learned about the test performance of POC antigen tests when used in this setting, these recommendations may change. Regardless of the results of the PCR test, both the POC antigen test result and the PCR test result must be reported to ECLRS.

Q30: If I test an **asymptomatic** individual in facilities or settings using a SARS-CoV-2 POC antigen test in a facility without an outbreak and the test is **negative**, should the negative result be confirmed?

A: No. A negative result in this situation does not require confirmation. Routing screening should be continued as described by CMS. See CMS Memo QSO-20-38-NH: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-additional-policy-and-regulatory-revisions-response-covid-19>.

Employees can continue to work, and the result must be reported to ECLRS.

Information for Nursing Homes

Q31: The Department issued Revised Skilled Nursing Facility Visitation guidance on September 17, 2020 which states that nursing homes must have an executed and operationalized arrangement with laboratories to process SARS-CoV-2 virus tests and that the test used should be able to detect SARS-CoV-2 virus with greater than 95% sensitivity and greater than 90% specificity. However, we are aware that the antigen tests being distributed by HHS may not meet these criteria for sensitivity and specificity. Can the antigen tests being distributed by HHS still be used to perform testing of our staff and residents?

A: Yes. On August 26, 2020, CMS published CMS Memo QSO-20-38-NH that states that facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. For additional information, see: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-additional-policy-and-regulatory-revisions-response-covid-19>.

Q32: 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 New York State nursing homes required to follow CMS testing requirements?

A: Yes.

Q33: Are New York State nursing homes required to follow New York State reporting requirements?

A: Yes.

Q34: Are New York State nursing homes required to follow the testing algorithm described above?

A: Yes.

Q35: 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 testing, prior to testing resident visitors. If a nursing home will be testing visitors, they will need to meet all New York State 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.