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Abbott ID NOW COVID-19 Assay
Frequently Asked Questions for Health Care Providers

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General Information

Q1: What is the Abbott ID NOW COVID-19 assay?

A: The Abbott ID NOW COVID-19 (ID NOW COVID-19 assay) is a molecular test used to detect the part of the SARS-CoV-2 virus called viral RNA (nucleic acid), which is the virus's genetic material. Molecular tests are different from antigen tests. SARS-CoV-2 antigen tests detect a part of the virus called viral proteins, which make up the virus's structure.

Q2: Is the ID COVID-19 NOW assay specific for SARS-CoV-2 or does it cross-react with other respiratory viruses?

A: Like most molecular tests, it targets a very small region of the viral RNA which is unique to the SARS-CoV-2 virus and in specificity studies was demonstrated to not react with other respiratory viruses, including other coronavirus such as SARS and MERS.

Q3: Is an instrument needed to perform the ID NOW COVID-19 assay?

A: Yes. The ID NOW COVID-19 assay is performed on a very small, lightweight, easily portable instrument called the Abbott ID NOW instrument.

Q4: What specimen types can be tested with the ID NOW COVID-19 assay?

A: Testing can be performed on nasal, nasopharyngeal or throat (oropharyngeal) swabs. Staff performing testing should read the *Instructions For Use* document for information on how to collect each specimen type.

Q5: Where can I find the ID NOW COVID-19 assay *Instructions For Use*?

A: The ID NOW COVID-19 assay *Instructions For Use* can be found at: https://www.fda.gov/media/136525/download

Q6: The instructions for the ID NOW COVID-19 assay indicate that the test is intended for use on symptomatic individuals within the first seven days of the onset of symptoms. Can these tests be used to test asymptomatic individuals?

A: Under federal law, and guidance, the ID NOW COVID-19 assay can be used by licensed health-care practitioners prescribing or administering this test, to perform testing on **asymptomatic individuals in congregate facilities, areas with outbreak situations, or other approved settings** using anterior nares (nasal) specimens, as the U.S. Department of Health and Human Services (HHS) has indicated that 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-incongregate-settings.pdf; https://www.cms.gov/files/document/qso-20-38-nh.pdf.

Obtaining Approval to Use the Abbott ID NOW

Q7: Our facility is not a laboratory, but the instructions for the ID NOW COVID-19 assay state that testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high, moderate, or waived complexity tests. Do we still need to be approved to perform testing using the Abbott ID NOW test?

A: Yes. Any facility performing testing using the ID NOW COVID-19 assay 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, local health departments, 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).

Q8: The FDA has designated the ID NOW COVID-19 assay as a waived test. What type of approval is needed from the Department to perform testing using the ID NOW COVID-19 assay?

A: If your facility is only using tests designated by the FDA as waived tests, such as the Abbott ID NOW, your facility will need to be registered as an 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.

Q9: Who issues an LSL registration?

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

Q10: Our facility does not have an LSL registration. How do we become approved?

A: To become registered, a facility 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.

Q11: Our facility already has an LSL registration. Should I add the ID NOW COVID-19 assay 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/clep/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. When adding the test, please specify COVID-19 molecular and include the name of the test (i.e., Abbott ID NOW COVID-19 assay).

Q12: Can a facility with an LSL perform testing off site?

A: Yes. However, if testing will occur at a location other than the address shown on the LSL registration, the LSL must request approval to perform Community Screening. To add Community Screening to an existing LSL, go to: https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs. Click on "Changing a Limited Service Laboratory Registration Certificate" and then choose "Add and/or Delete Test Procedures". Next to test procedure name, indicate request Off-Site Community Screening approval. Laboratory staff bring testing equipment from the registered LSL to an off-site location where specimen collection and testing will occur. At the end of the event, staff, equipment & records must be returned to the registered LSL location.

Q13: If we have questions about obtaining or updating LSL registrations, whom 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.

Q14: Since this is a waived test, can a facility with a NYS CLEP permit for high complexity testing perform this test without applying for expansion of permitted categories?

A: No. Laboratories holding permits for high complexity testing need to hold approval for Virology molecular testing in order to perform the Abbott ID NOW test. If this is the only Virology test to be performed, a limited expansion to the permit can be allowed.

Q15: Are there requirements for staff collecting specimens?

A: On March 15, 2020, a health advisory was issued regarding specimen collection by unlicensed individuals. 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 training is required. See: https://coronavirus.health.ny.gov/system/files/documents/2020/05/doh_covid19_advisoryswabtrainingunlicensedindividuals_final-5.15.20.pdf

Reporting of Test Results

Q16: If our facility is performing testing with the ID NOW COVID-19 assay, do we need to report test results to New York State?

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

Q17: 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 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 code;
- ordering provider phone number;
- performing facility name and CLIA number;
- performing facility full address with zip code;
- specimen source (type);
- 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.

Q18: How often does this information need to be reported?

A: Information needs to be reported immediately (within 3 hours) through ECLRS.

Q19: 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 the Abbott ID NOW Test

Q20: There have been reports of false negative test results when using the ID NOW COVID-19 assay. If a negative result is obtained, is additional testing required?

A: The ID NOW COVID-19 assay was authorized by the FDA for use on symptomatic individuals within the first seven days of the onset of symptoms. Under these circumstances, Abbott has indicated in their *Instructions For Use* document that negative results should be treated as presumptive. Although HHS has indicated that federal law and guidance permits the use of the ID NOW COVID-19 assay to perform testing on asymptomatic individuals in congregate settings using anterior nares (nasal) specimens, data on test performance in these circumstances are not available. The actions taken after performing testing with the ID NOW COVID-19 assay will depend on if the individual tested

is symptomatic or asymptomatic and if the test is used in an outbreak/high prevalence area or in a non-outbreak/low prevalence area.

Q21: Is there a testing algorithm that can be used to determine steps that need to be taken when using the ID NOW COVID-19 assay?

A: Yes. Testing algorithms have been developed describing how the ID NOW COVID-19 assay can be used when:

- testing symptomatic individuals or asymptomatic individuals associated with a congregate setting (as defined in Q6) in an outbreak/high prevalence area.
- testing symptomatic individuals or asymptomatic individuals in associated with a congregate setting (as defined in Q6) in a non-outbreak/low prevalence area.

These algorithms are attached to this document. The testing algorithms describe if a confirmatory lab-based SARS-CoV-2 molecular test is needed and the actions to be taken if the confirmatory test is positive or negative.

Use of the ID NOW COVID-19 Assay in an Outbreak/High Prevalence Area (see attached algorithms)

Q22: If I test a ***symptomatic*** individual in an area with **an outbreak/high prevalence** using the ID NOW COVID-19 assay, and the 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, contact tracing) must be taken.

Q23: If I test a ***symptomatic*** individual in an area with **an outbreak/high prevalence** using the ID NOW COVID-19 assay, and the test is ***negative***, does the negative result need to be confirmed?

A: As indicated in the ID NOW COVID-19 assay *Instructions For Use* document, negative results for symptomatic individuals should be treated as presumptive and, if inconsistent with clinical signs and symptoms or if necessary for patient management, should be tested with a different authorized or cleared molecular test. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. A confirmatory laboratory-based SARS-CoV-2 molecular test should immediately be performed in conjunction with testing for other respiratory pathogens. The individual should be quarantined until the laboratory-based molecular test results are obtained.

- If the confirmatory laboratory-based molecular test is positive, isolation must be continued, and contact tracing initiated.
- If the confirmatory laboratory-based molecular test is negative, quarantine can be discontinued.

Regardless of the results of the laboratory test, both the ID NOW COVID-19 assay test result and the confirmatory test result must be reported to ECLRS.

Q24: If I test an ***asymptomatic*** individual associated with a **congregate setting** in an area with **an outbreak/high prevalence** using the ID NOW COVID-19 assay, and the test is ***positive***, does the positive result need to be confirmed?

A: No. A positive result in an area with an outbreak/high prevalence does not require confirmation. The result must be reported to ECLRS, and the appropriate actions (e.g. isolation and contact tracing) must be taken.

Q25: If I test an ***asymptomatic*** individual associated with a **congregate setting** in an area with **an outbreak/high prevalence** using the ID NOW COVID-19 assay, and the test is ***negative***, does the negative result need to be confirmed?

A: Due to the potential for a false negative result with the ID NOW in this setting, a confirmatory test with a laboratory-based molecular test for SARS-CoV-2 should be considered. Negative results should be considered in the context of a patient's recent exposures, and a detailed thorough history needs to be taken to ensure that the patient does not have clinical signs and symptoms consistent with COVID-19. Specimen collection for the confirmatory test should occur **on the same day** that the ID NOW COVID-19 assay was performed. If this is not possible, it can be collected **up to a maximum of 48 hours** later. Note that data on the performance of the ID NOW COVID-19 assay on asymptomatic individuals in a congregate setting is not yet available and the value of a confirmatory test is higher in areas where the virus is prevalent **and when performed closer in time to the collection of the initial specimen**. If a follow-up laboratory-based molecular test is performed, then the individual should be quarantined until the PCR test results are obtained.

- If the confirmatory laboratory-based molecular test is positive, isolation must be continued, and contact tracing initiated.
- If the confirmatory laboratory-based molecular test is negative, quarantine can be discontinued.

Regardless of the results of the laboratory-based test, both the ID NOW COVID-19 assay test result and the confirmatory test result must be reported to ECLRS.

<u>Use of the ID NOW COVID-19 Assay in a Non-Outbreak/Low Prevalence Area (see attached algorithms)</u>

Q26: If I test a ***symptomatic*** individual in **a non-outbreak/low prevalence** area using the ID NOW COVID-19 assay, and the 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 and contact tracing) must be taken.

Q27: If I test a ***symptomatic*** individual in **a non-outbreak/low prevalence** area using the ID NOW COVID-19 assay, and the test is ***negative***, does the negative result need to be confirmed?

A: As indicated in the ID NOW COVID-19 assay *Instructions For Use* document, negative results for symptomatic individuals should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with a different authorized or cleared molecular test. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. A confirmatory test with a laboratory-based molecular

test for SARS-CoV-2 should immediately be performed in conjunction with testing for other respiratory pathogens. The individual should be quarantined until the confirmatory test results are obtained.

- If the confirmatory laboratory-based molecular test is positive, isolation must be continued, and contact tracing initiated.
- If the confirmatory laboratory-based molecular test is negative, quarantine can be discontinued.

Regardless of the results of the laboratory-based test, both the ID NOW COVID-19 assay test result and the confirmatory test result must be reported to ECLRS.

Q28: If I test an ***asymptomatic*** individual in a **congregate setting** in **a non-outbreak/low prevalence** area using the ID NOW COVID-19 assay, and the test is ***positive***, does the positive result need to be confirmed?

A: Yes. Due to the potential for a false positive result, a confirmatory test with a laboratory-based molecular test for SARS-CoV-2 should be performed on a specimen collected **within 48 hours** and **preferably the same day** that the ID NOW COVID-19 assay was performed. The individual should be quarantined until the PCR test results are obtained.

- If the confirmatory laboratory-based molecular test is positive, isolation must be continued, and an outbreak response initiated.
- If the confirmatory laboratory-based molecular test is negative, quarantine is not necessary unless the patient has become symptomatic.
- If the confirmatory laboratory-based molecular test result is not available within 3-days after performing the ID NOW COVID-19 assay, the facility should continue with other appropriate actions such as isolation/exclusion.

As more is learned about the test performance of the ID NOW COVID-19 assay when used in this setting, these recommendations might change. Regardless of the results, both the ID NOW COVID-19 assay test result and the confirmatory results must be reported to ECLRS.

Q29: If I test an ***asymptomatic*** individual in a **congregate setting** in a **non-outbreak/low prevalence** area using the ID NOW COVID-19 assay, and the test is ***negative***, should the negative result be confirmed?

A: No. A negative result in this situation does not require confirmation and the result must be reported to ECLRS. However, negative results should be considered in the context of a patient's recent exposures, and a detailed thorough history needs to be taken to ensure that the patient does not have clinical signs and symptoms consistent with COVID-19.

Additional Information

Q30: Are training materials available for the ID NOW COVID-19 assay?

A: Yes. Training videos are available at: https://www.globalpointofcare.abbott/en/support/product-installation-training/id-now-training-videos.html.

Q31: Can you provide any additional guidance regarding the operation of the ID NOW COVID-19 assay, especially when used outside of a laboratory setting (e.g., out in the field)?

A: Yes. Based on the Department's experience, there are several suggestions that can be helpful for troubleshooting purposes.

Invalid Results:

- If the unit presents with an invalid result:
  - Carefully remove the white transfer cartridge with the orange test base that is now attached to it and inspect the two small glass vials at the bottom of the orange test base. Note if the reagent solution entered and dissolved the powder reagents, or if there is undissolved white powder in the glass vials. This is the commonest cause of invalid results and usually indicates that the cartridge was not pushed down firmly enough.
  - Run another test, taking care to press the white cartridge firmly with both hands, first into the blue sample receiver until you hear the "click" and the orange button on the top of the cartridge pops up, then into the orange test base until you hear the "crunch" and the orange button on the top of the cartridge pops back down. Consider switching operators to rule out user error.
  - If reagent solution repeatedly fails to enter the vials, attempt to run the test with a different lot number of cartridges, if available.
- If the unit still presents with repeated invalid results and/or they are not the result of undissolved reagent, proceed with the following:
  - Shut the unit down using its power button.
  - Unplug the unit.
  - Let the unit sit unplugged for approximately 5 minutes.
  - Ensure the unit's fan has adequate ventilation and is not obstructed by a wall or other objects before powering back up.
  - Plug the unit back into the power source.
  - Restart the unit using the power button.
  - Wait for the unit to go through its entire power-up (boot) cycle.
  - When prompted, re-enter the username and password.
  - Wait for the unit to run its self-test, then wait approximately 1 minute after the self-test completes.
  - Select "RUN QC TEST".
  - Run a positive control test 1st.
  - Run a negative control test 2nd.
  - If the unit passed both positive and negative controls, select "RUN TEST" on menu and proceed with testing.

Other Troubleshooting Suggestions:

- If the unit is plugged into a long extension cord, change to a better gauge (i.e. minimum 16 gauge).
- More than one unit should never be plugged into a power strip.
- If the unit's fan (located on the rear of the unit) is obstructed, remove obstacles to improve ventilation to avoid overheating of the unit.

- Make sure there is no splashing when the swab is swirled in the solution. You must mix it well and squeeze the swab against the side, but if you splash, you will contaminate the machine and invalidate the results.
- The following steps should ensure that sufficient specimen and solution enters the cartridge and from there, are mixed with the reagents in the test base
    - When you attach the white cartridge to the blue sample receiver, press down with two hands to make sure it “clicks” and the orange button on the top of the cartridge pops up.
    - Make sure to WAIT until the machine instructs you to move to the next step. It is very tempting to do it too quickly before you should. If you do it will invalidate the test.
    - When moving the white cartridge to the orange test base, lift it straight up and over, ensuring that the plastic tips on the bottom of the cartridge do not touch the outside of the blue sample receiver or the edge of the orange test base before lowering it into the test base.
    - Press the white transfer cartridge down firmly into the orange test base with two hands, until you hear a “crunch” and see the orange button on the top of the white cartridge pop back down.
- Make sure the unit was unplugged since its last operational period (usually the day before).
- Close the lid gently. Do not close the lid abruptly, or you will invalidate the test.
- The unit must operate in an ambient environment (and unit temperature) of less than 86° F and less than 80% humidity. You will get invalid results if either is higher.

Q32: Can you provide any additional guidance regarding infection control measures needed when performing testing using the ID NOW COVID-19 assay in a congregate setting?

- Follow guidelines from the Centers for Disease Control and Prevention’s “Performing Broad-Based Testing for SARS-CoV-2 in Congregate Settings,” when applicable. Specifically:
    - Ensure appropriate PPE and supplies are available.
    - Ensure the physical space is appropriate for mass testing. For individuals at risk of severe illness from COVID-19, such as residents of long-term care facilities, specimen collection should be performed one at a time in each resident’s room with the door closed with only the individual being tested and the testing team present.
    - Develop a plan of how individuals will flow through functional stations, if applicable.
    - Clean and disinfect all environmental surfaces using an Environmental Protection Agency-registered disinfectant from List N (available at: https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19).
    - Ensure the Abbott ID NOW instrument is cleaned and disinfected according to the manufacturer’s instruction.