



Testing Asymptomatic Patients in Alaska Using Abbott ID NOW COVID-19 Test

The Alaska State Public Health Laboratories sought guidance from the CMS/CLIA Division of Clinical Laboratory Improvement and Quality and the Centers for Disease Control and Prevention (CDC) regarding asymptomatic patients and COVID-19 testing. This letter describes the response from these entities.

The following question was posed to the CLIA LAB Excellence mailbox (April 22, 2020):

If a patient is asymptomatic, and does not have signs or symptoms of COVID-19 or respiratory illness, does testing these patients go against the package insert, making the test high complexity?

The response from the CMS/CLIA Division of Clinical Laboratory Improvement and Quality:

"The intended use in the Instructions for Use (IFU) for the Abbott ID Now COVID-19 test system states "...intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider. As such, the decision to test an individual (symptomatic or asymptomatic) is up to the individual's healthcare provider. The CLIA regulations at §493.1241 state that the laboratory must have a written or electronic request for patient testing from an authorized person. An authorized person is defined in the regulations as an individual authorized under State law to order tests or receive test results, or both. The State law determines who (e.g., healthcare provider) may order a test. Just as a note: The Performance Characteristics, Clinical Study section states the following: The performance of ID NOW COVID-19 was evaluated using contrived clinical nasopharyngeal (NP) swab specimens obtained from individuals with signs and symptoms of respiratory illness.

For any further questions, please contact the FDA at COVID19DX@fda.hhs.gov."

The following question was posed to the CDC during an Association of Public Health Laboratory Meeting (April 29, 2020):

If a patient is asymptomatic, and does not have signs or symptoms of COVID-19 or respiratory illness, can the patient be tested using the Abbott ID NOW?

The response from the CDC:

PRIORITIES FOR COVID-19 TESTING (Nucleic Acid or Antigen) - <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html> High priority testing is reserved for 1) Hospitalized patients with symptoms, 2) Healthcare facility workers, workers in congregate living settings, and first responders with symptoms, 3) Residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms, and 4) Persons identified through public health cluster and selected contact investigations. Priority testing is reserved for 1) Persons with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea and/or sore throat, and 2) Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.

From this information at this point in the outbreak, the Alaska State Public Health Laboratories promote the following:

- Testing sites performing the ID NOW COVID-19 test must have a current CLIA Certificate of Waiver.
- The health care provider is responsible for the decision to test an individual, and testing asymptomatic individuals using the Abbott ID NOW does not make the test high complexity; it can continue to be used under a CLIA Certificate of Waiver.
- During the COVID-19 public health emergency, CMS will permit a Certificate of Waiver laboratory to extend its existing CLIA Certificate of Waiver to operate a COVID-19 temporary testing site in an off-site location, such as a long-term care facility or correctional facility. The temporary site is only permitted to perform waived tests, including the Abbott ID NOW system, consistent with the laboratory's existing Certificate, and would be under the direction of the existing lab director.
- Asymptomatic people can be tested on the Abbott ID NOW under the discretion of public health monitoring, sentinel surveillance, or screening according to state and local plans.

Please pose any questions regarding these regulations to katherine.ross@alaska.gov or to the DHSSEOC@alaska.gov.