

Alaska Section of Epidemiology (SOE)

Guidance for Coronavirus Disease 2019 (COVID-19) Testing in Alaska

August 19, 2020

Key Points

- On June 1, 2020, FDA issued an [amendment](#) for the Abbott ID NOW COVID-19 assay to include the following:
 - Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, the patient should be reswabbed and tested with different authorized or cleared molecular tests.
- Providers should base their decision about where to submit specimens primarily on turnaround time and practicality rather than the lower limits of detection of the various PCR analyzers.
- Providers no longer need to submit a specific COVID form to alert SOE about testing.
- Providers must report laboratory-confirmed cases of COVID-19 to SOE by either leaving a message on the COVID Reporting Hotline (**1-877-469-8067**) or via fax using the [standard Infectious Disease report form](#). See page 2 for reporting information for point-of-care and in-house testing.
- SOE staff can be reached for consultation at **907-269-8000** or **800-478-0084** (after-hours).
- The [Alaska State Public Health Laboratory](#) (ASPHL) is running specimens a combined 7 days a week in their Anchorage or Fairbanks facilities. STAT testing is generally not being offered.
- Anyone with symptoms who is being tested for COVID-19 should be informed to act as if they have COVID-19 until a result comes back. SOE guidance on what outpatients should do if they have COVID-19 or if a COVID-19 test is pending is available [here](#).
- CDC guidance for discontinuation of home isolation for persons with COVID-19 is available [here](#).

Test Anybody in Alaska Who is Experiencing Symptoms of COVID-19

- Symptoms of COVID-19 may include any of the following: fever, cough, shortness of breath, difficulty breathing, chills, decreased appetite, diminished sense of taste or smell, diarrhea, fatigue, headache, muscle/joint aches, nausea, rash, rigors, runny nose, sore throat, or sputum production.
- Have a low threshold to test any patient with new, unexplained symptoms that may be clinically compatible with COVID-19.

Targeted Testing for Asymptomatic Persons

- Per [Mandate 10 or 17](#) or as required per local communities
 - Upon admission to a health care facility
 - For patients undergoing urgent/emergent procedures that put health care personnel at high exposure risk
- Other settings where asymptomatic testing may be considered
 - [All close contacts of confirmed COVID-19 patients](#)
 - Health care workers in hospitals and congregate living settings
 - Residents in congregate living settings (see DHSS guidance for specific groups)
 - Other high-consequence settings (e.g., people coming in to remote communities from areas where COVID-19 is circulating)
 - People involved in discrete outbreaks (in consultation with public health)
 - Other patients who may be at increased risk for infection, per the discretion of a clinician

Where to Route Specimens

- Different molecular analyzers have different lower limits for the quantity of viral RNA they are able to detect per mL of specimen obtained (i.e., some instruments are more sensitive than others).

However, the quantity of virus people shed at any given time during the course of their infection has not been well characterized, and so it is unclear if the various sensitivities of the different analyzers make a meaningful difference in their ability to detect infection in patients.

- Until further clinically-relevant data become available, we suggest that providers base their decision about where to submit specimens primarily on turnaround time and practicality.

Guidance for Facilities with Their Own COVID-19 Molecular Laboratory Testing Capacity

- On June 1, 2020, FDA issued an [amendment](#) for the Abbott ID NOW COVID-19 assay to include the following:
 - Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, patients should be reswabbed and tested with different authorized or cleared molecular tests.
 - Positives obtained by the provider do not need to be CONFIRMED by the state public health laboratories. If they want to confirm, they must collect a new specimen in VTM and send to the public health labs.
- Facilities with their own molecular diagnostic testing capacity for COVID-19 should develop criteria for testing prioritization based on facility capacity and local community needs or testing strategy.
- Providers must report lab-confirmed cases of COVID-19 to SOE by either leaving a message on the COVID Reporting Hotline (**1-877-469-8067**) or via fax using the [Infectious Disease report form](#).
- In addition, all results (i.e., positive, negative, indeterminate, etc.) must be reported via either integration into existing electronic laboratory reporting (ELR) data feeds or fax (907-563-7868). Please email Megan Tompkins (megan.tompkins@alaska.gov) to inform us about how your facility will report. Contact ASPHL at 334-2100 to request a proficiency testing kit.
- Mail all *positive* specimens to the Alaska State Virology Laboratory (ASVL) for whole genome sequencing, per the shipping instructions available [here](#). Positives can be batched and sent in once per week. This does not require a recollection; ASVL will sequence from the original specimen.
- Follow in-house testing manufacturer’s directions exactly when doing COVID-19 testing. EUA instructions may be different from in vitro diagnostic (IVD) instructions.

Specimen Type and Priority (based on [CDC Guidance](#))

- FDA guidance on swabs and specimen transport media is available [here](#).
- Please refer to the Table below to determine the appropriate swabs to use for testing.

Swab Type	NP	OP	Mid-turbinate	Nasal
Nasopharyngeal swab with tips made of polyester, rayon, or flocked nylon	Yes	Yes	Yes	Yes
Flocked tapered swab	No	No	Yes	Yes
Flocked or spun polyester swab	No	No	Yes	Yes
3D printed swabs	Yes	Yes	Yes	Yes
Cotton	No	No	No	No
Calcium alginate	No	No	No	No
Wood or metal (non-aluminum) shaft	No	No	No	No
Aluminum shaft	Yes	Yes	Yes	Yes

- All swabs should be placed in a transport tube containing either viral/universal transport medium, Amies transport medium, sterile RNase-free saline or phosphate buffered saline (PBS).

- NOTE: Swab samples for testing on the [Abbott ID Now](#) instrument should be placed directly into the instrument for testing. They should not be placed in any other media as this can reduce the sensitivity of the test through dilution, which can potentially lead to false negative result.
- An NP collection guidance video is available [here](#). A self-collection guidance video is available [here](#).
- Lower respiratory tract specimens, if available.
 - For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended.
 - When it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen.
- Maintain [proper infection control](#) when collecting specimens. See [Biosafety FAQs](#) for handling and processing specimens from suspected case patients.

Additional Specimen Collection Information

- ASPHL: see [Laboratory Test Directory \(page 23\)](#); specimens must be submitted with a [COVID Test Request form](#). Specimens are batched and current turnaround time is 1–3 days.
- Consult individual commercial labs for specific instructions.

Accuracy

- The accuracy of SARS-CoV-2 molecular diagnostic tests have not been systematically evaluated.
- Their specificity is generally considered to be excellent (>99%).
- Their sensitivity is variable; reported false-negative rates have ranged from <5% to >30%.
- Sensitivity depends on the type and quality of the specimen obtained, the duration of infection at the time of testing, and the specific assay.

Antigen Testing

- Tests that identify SARS-CoV-2 antigen are starting to appear on the market and the FDA has started to issue emergency use authorizations for some of these tests.
- The main advantages of these tests are that they are point-of-care with quick results and have high specificity.
- The main disadvantage is they are typically less sensitive than molecular diagnostic tests.
- Negative antigen test results should be confirmed using a sensitive molecular diagnostic test when the clinical suspicion is high.
- On August 5, [CSTE updated the case definition for COVID-19](#). Cases with positive results via antigen testing are now classified as “probable”. The public health response, i.e., case investigation and contact tracing, is the same for these cases as for “confirmed” cases, i.e., those with positive results via molecular testing methods.
- More information about antigen testing from CDC can be found [here](#).
- As with molecular testing, providers must report cases positive for COVID-19 via antigen testing to SOE by either leaving a message on the COVID Reporting Hotline (**1-877-469-8067**) or via fax using the [Infectious Disease report form](#). In addition, all results (i.e., positive, negative, indeterminate, etc.) must be reported via either integration into existing electronic laboratory reporting (ELR) data feeds or fax (907-563-7868). Please email Megan Tompkins (megan.tompkins@alaska.gov) to inform us about how your facility will report.
- Mail all *positive* specimens to the Alaska State Virology Laboratory (ASVL) for whole genome sequencing, per the shipping instructions available [here](#). Positives can be batched and sent in once per week. This does not require a recollection; ASVL will sequence from the original specimen.

Guidance on Serologic Testing

- Please read the Infectious Diseases Society of America (IDSA) Guidelines on the Diagnosis of COVID-19 regarding serologic testing [here](#).
- CDC's webpage for COVID-19 Serology Surveillance is available [here](#).
- At this time, serological tests should not be used as an alternative to molecular detection tests for the diagnosis of COVID-19 in symptomatic patients. Regardless of their serologic results, symptomatic patients should be tested for COVID-19 via molecular methods.
- Interpreting positive serologic test results can be particularly difficult in persons who did not have a prior clinically compatible illness and a positive RT-PCR test for COVID-19.
 - When the prevalence (or pre-test probability) of infection is <5%, a test with a specificity between 96%-98% will be more likely to give a false positive than a true positive result. The prevalence of prior SARS-CoV-2 infection is likely <1% in the general Alaska population at this point. We do not yet have a good understanding of the specificity of the various serologic assays for COVID-19.
 - Cross-reactivity with other common coronaviruses may also lead to false-positive serologic test results.
- Even if a person does have antibodies to SARS-CoV-2, whether these antibodies confer immunity is unknown. Therefore, IDSA recommends that antibody tests not be used to make decisions about whether personal protective equipment is needed.
- Providers must report lab-confirmed cases of COVID-19 to SOE by either leaving a message on the COVID Reporting Hotline (**1-877-469-8067**) or via fax using the [Infectious Disease report form](#). In addition, all results (i.e., positive, negative, indeterminate, etc.) must be reported via either integration into existing electronic laboratory reporting (ELR) data feeds or fax (907-563-7868). Please email Megan Tompkins (megan.tompkins@alaska.gov) to inform us about how your facility will report.

Note: *Because the sensitivity of all COVID-19 tests is <100%, a negative test result does not rule out infection. This is a particularly important point to consider when caring for patients with a clinically compatible illness and known contact to a confirmed case.*

Please check the [DHSS COVID-19 website](#) and [CDC's COVID-19 website](#) frequently for updates.