Alaska Section of Epidemiology (SOE)
September 29, 2020

Key Points
- 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 Laboratories in Anchorage (ASPHL) and Fairbanks (ASVL) are running specimens 7 days a week at both 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.
- Providers should have a low threshold to test any patient with new, unexplained symptoms that may be clinically compatible with COVID-19.
- There are currently no confirmed reports of a person being re-infected with COVID-19 within 3 months of initial infection. However, a positive test in a prior case with onset of new symptoms should not necessarily be ruled out as a residual infection. Consult with SOE regarding the possibility for second cases.

Targeted Testing for Asymptomatic Persons
- Per Mandate 10 or 15 or as required per local communities:
  - Upon admission to a health care facility
  - Patients who may be at higher risk of spreading COVID-19, including those who require aerosolizing procedures such as suctioning, intubation, or breathing treatments or delivery
  - Patients at higher risk for complication associated with intubation if COVID positive
- 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
- Asymptomatic persons who have had a positive test in the past 90 days should NOT be re-tested.

Where to Route Specimens
- Different 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 September 17, 2020, FDA issued an amendment for the Abbott ID NOW COVID-19 assay and its Instructions for Use. Changes include:
  - The assay is intended for detection from individuals within the first 7 days of symptom onset.
  - For best performance, it is highly recommended the test swab is placed in a clean, unused tube, capped tightly, and stored at room temperature for up to 1 hour prior to testing. If greater than a 1 hour delay occurs, dispose of sample and re-test the individual.

- Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, patients should be re-swabbed and tested with different authorized or cleared molecular tests.

- Positives from symptomatic individuals obtained by the provider do not need to be confirmed by the ASPHL or ASVL. If they want to confirm, they must collect a new specimen in the appropriate transport media and send to ASPHL or ASVL.

- 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, submission of a standard format csv via SFTP, or fax (907-563-7868). Please email Megan Tompkins (megan.tompkins@alaska.gov) at SOE to inform us about how your facility will report.

- Contact ASPHL at 907-334-2100 to request a small panel of samples to verify the capability of their analyzer to detect the virus.

- Send all positive specimens as Category B samples to ASVL in Fairbanks for whole genome sequencing, per 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.

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

Alaska Division of Public Health, Section of Epidemiology | Phone: 907-269-8000 | Afterhours: 800-478-0084
Fax: 907-563-7868 | Email: infdisease@alaska.gov | Website: http://dhss.alaska.gov/dph/Epi/Pages/default.aspx
• 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 results.
• An NP collection guidance video is available here. A self-collection guidance video is available here.
• Testing may be performed on lower respiratory tract specimens, if available.
  o For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended.
  o 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 and ASVL: 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.

Molecular Diagnostic Testing 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 on the market and the FDA has issued 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.
• For symptomatic persons or those who are being tested while in quarantine:
  o If the test is positive, no further test is needed and the person is positive for COVID-19.
  o If the test is negative, a second swab should be collected and a PCR test should be performed for the person; they should continue isolating themselves until the PCR test result comes back.
• For asymptomatic persons with no known exposures who are being screened for COVID-19:
  o If the test is positive, a second swab should be collected and a PCR test should be performed for that person to confirm the positive. They should isolate themselves until the PCR test result comes back.
  o If the test is negative, the person should be considered negative and a confirmatory PCR test is not needed.
• 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, submission of a standard format csv via SFTP, or fax (907-563-7868). Please email Megan Tompkins ([megan.tompkins@alaska.gov](mailto:megan.tompkins@alaska.gov)) to inform us about how your facility will report.

**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 or 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.
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**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.