



## Guidelines for Laboratories Performing Waived COVID-19 Testing in Alaska (June 26, 2020)

### Key Points

- All Labs must have a valid CLIA Certificate to test patient samples.
- A test is considered CLIA waived if it has an EUA application and Letter of Authorization from the FDA and the package insert contains language like 'outside the clinical laboratory, near patient testing, point of care' or similar.
- The Abbott ID NOW and Cepheid Xpert Xpress SARS-CoV-2 are deemed CLIA waived for the duration of the EUA period.
- Follow the manufacturer's instructions.
- The sensitivity of these waived tests is much less than other methods, which could lead to false-negative results.

### Due to the sensitivity concerns of the analyzers, the Alaska Public Health Laboratory (ASPHL) and the Alaska Virology Laboratory (ASVL) can provide confirmatory testing if requested.

1. Confirmation testing is available for negative specimens if patient symptoms are inconsistent with the result. It is unnecessary to send all negatives for confirmation.
2. Confirmation testing is not required for positives. However, if you do have positives, please batch the tested specimens weekly and ship to the Alaska State Virology Laboratory for sequence analysis (no recollection necessary).
3. If confirmation testing is requested, please submit a newly collected swab in VTM or UTM. Do not send Abbott ID buffers or the remains from previously tested specimens at this time.
  - A separate [requisition](#) form is provided to identify these as confirmation tests.
  - Universal or viral transport media (UTM or VTM) will be provided if needed. Contact the State EOC at 907-428-7100
  - Store sample in the freezer until ready to ship.
  - Send the labeled sample and requisitions as Category B with ice packs to either State Lab.

### Verification Panels

ASPHL has prepared a proficiency panel of 2 positive and 1 negative samples as a way for you to ensure your analyzer is performing correctly. Contact ASPHL at 334-2100 if you would like a set (one set per instrument), and indicate on which instrument the samples will be run.

### Reporting Results

- Follow the manufacturer's instructions for reporting results, including any comments or interpretations.
- Report all test results to the Section of Epidemiology (SOE) at 907-269-8000. Fax all positive results to SOE at 907-563-7868.

### Safety

- Maintain proper infection control when collecting specimens. See Biosafety FAQs for handling and processing specimens. <https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html>

### Good Laboratory Practices

- Follow good laboratory practices as outlined in the CDC's "Ready? Set? Test!" Booklet: [www.cdc.gov/labquality/waived-tests.html](http://www.cdc.gov/labquality/waived-tests.html)

### Resources

- Alaska DHSS COVID-19: <http://dhss.alaska.gov/dph/Epi/id/Pages/COVID-19/default.aspx>
- Alaska Public Health Laboratories: <http://dhss.alaska.gov/dph/Labs/Pages/default.aspx>; see Alaska PHL COVID Testing Guidance at: <http://dhss.alaska.gov/dph/Labs/Pages/COVID.aspx>