



## Guidelines for Emergency Testing Authorization for COVID-19 in Alaska (April 24, 2020)

*These guidelines are subject to change as the testing capacity and the public health emergency evolves or if the State Agency receives any updates from CMS, CDC, and/or the FDA.*

### Summary

The purpose of this letter is to update Alaska Laboratories about regulations for COVID-19 testing in Alaska.

### Key Points

- The CLIA regulations have not changed. The FDA's process for reviewing and authorizing tests has changed to respond to the COVID-19 pandemic.
- Currently there are no FDA-approved or cleared tests to diagnose or detect COVID-19 because the virus that causes COVID-19 is new. Therefore, the FDA issues Emergency Use Authorizations (EUAs) for the use of new diagnostic tests to detect the SARS-CoV-2 virus, which causes COVID-19. During public health emergencies declared under section 564 of the FD&C Act, the FDA is able to issue EUAs when certain criteria are met that allows for the use and distribution of potentially life-saving medical products to diagnose, treat, or prevent the disease, which can include diagnostic tests.
- Follow the manufacturer's instructions.
- **The decision to test an individual (symptomatic or asymptomatic) is up to the individual's health care provider.**

### Waived Tests

- 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 considered CLIA waived for the duration of the EUA period.
- The waived status may change after the termination of the EUA. Be prepared to discontinue the testing or upgrade to a moderate or high complexity certificate if this occurs.

### Non-Waived Testing

- Non-waived COVID-19 tests are subject to all applicable CLIA regulations, including verification of performance specifications, personnel competency, and laboratory director responsibilities. A COVID-19 test system must have an EUA submission and a Letter of Authorization from the FDA with a statement in the package insert indicating whether the test system can be used in a moderate or high complexity laboratory.

### High Complexity Testing

- If a test system does not have an EUA submission to the FDA and a Letter of Authority, the test is considered High Complexity, regardless of what the package insert states.

### Serology Testing

- All serology tests must have an EUA submission and Letter of Authorization from the FDA and the package insert must state if the test is considered waived, moderate, or high complexity. If there is no EUA/Letter of Authority, the test is automatically considered high complexity.

### References

- Information on CLIA: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>
- FDA: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- CDC: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>
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