| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 02D0674496 | 02/09/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Alaska State Public Health Laboratory | 5455 Dr Martin Luther King Jr Ave, Anchorage, AK | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS-209 laboratory personnel report form and interview with the laboratory manager on 02/11/2021 the laboratory failed to establish and follow written policies and procedures to assess employee competency annually. Findings include: 1. The laboratory's CMS-209 personnel form identified six individuals who are identified as technical supervisors (TS), of which three of the six are identified as general supervisors (GS) and all six are also testing personnel. 2. The two of the six individuals identified as TS had no competency assessments as testing personnel for the testing in which they perform. 3. Two of the six identified TS had a checklist of annual testing personnel competency completed which were not signed by the laboratory director. TS- (C) Start Date 6/17/2020 No six month competency performed. TS-(D) No annual competency 2019, 2020 4. Three of three testing personnel for the Toxicology laboratory had no annual competency's performed for 2019, 2020. The General Supervisor had performed assessments on all three (one on themselves) for 2020, which had not been reviewed or approved by the laboratory director. 5. The laboratory technical supervisor (A) confirmed the lack of competency assessments for Technical supervisors/General supervisors by interview on February 09, 2021 at 10:20 a.m. 6. The laboratory reports performing 283,025 patient samples annually. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a) |

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| | The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview with the laboratory personnel on 02/08/2021, the laboratory failed to follow established written policies and procedures for each of the following, if applicable: Specimen storage and preservation, Conditions for specimen transportation. The findings include: 1. The laboratory utilizes the Fairbanks Public health laboratory's VTM media for SARS CoV-2 specimen transport to the public health labs from collection sites around the state. The validation study established the stability for SARS CoV-2 tests at 2-8 Celsius once inoculated for up to 7 day or frozen at -70 degrees. 2. On entrance to the laboratory facility on 02/08/2021, it was observed that a commercial cooler had been placed at the entrance reception area for specimens to be dropped off. Upon closer review it was noted that on the lid of the cooler a flyer was posted stating "do not close the lid". Inside the cooler was a cool pack and patient specimens. The cooler did not have a thermometer to monitor the temperature of the internal cooler space through out the day. 3. On 02/09/2021 at 08: 30 a.m. it was observed an individual carrying in two patient specimens and placing them into the cooler. Review of the cooler contents at 10:00 a.m. revealed the cooler now had over 30 patient samples awaiting testing. The laboratory has no policy or procedure for monitoring the temperatures of the cooler during the day as increased numbers of patient samples are placed in the open cooler over time. 4. The laboratory performs SARS CoV-2 testing on the Panther Aptima system on nasal swabs and Thermofisher MagMax Multiplex Real Time rt-PCR methodologies collected in the ASPHL VTM media validated for storage at 2-8 Celsius. The Laboratory had no documentation of specimen temperatures upon receipt to determine acceptability. 5. Upon interview with the department technical supervisors A, B,and C on 01/08/2021, it was revealed that the laboratory does not monitor and document the temperatures of patient VTM SARS CoV-2 specimens for acceptability upon receipt prior to testing. 6. The laboratory technical supervisors A,B, and C confirmed by interview on January 09, 2021 at 10:00 a.m. the lack of monitoring and documenting specimen temperature acceptability. 7. The laboratory reports performing 242,183 SARS CoV-2 molecular tests annually. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on patient record review and interview with the laboratory Technical Supervisor B on 01/08/2021, the laboratory failed to ensure test report indicated the correct name and address of the laboratory location where the test was performed. The finding include: 1. A random patient record review from March 1, 2020 through February 02, 2021 revealed that patient testing performed on 06/13/2020 for lab ID 2016400258 had been reported as being performed at the Fairbanks Public Health laboratory. 2. The laboratory TS (B) and the Quality Assessment personnel confirmed that the specimen had been sent to the Anchorage laboratory due to reagent shortage at the Fairbanks location. The laboratory information system assigns the location automatically by the identification number. The number had not been reassigned prior to release of the patient report. 3. The laboratory Technical Supervisor (B) confirmed by interview on 02/09/2021 at 10:00 a.m. that the test had been performed at the Anchorage laboratory and the test report was not accurate. 4. The laboratory reports performing 283,025 patient specimens annually. |