

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D0674508	<b>(X3) Date Survey Completed</b>  02/12/2021
<b>Name of Provider or Supplier</b>  Alaska State Virology Laboratory	<b>Street Address, City, State</b>  1051 Sheenjek Drive, Fairbanks, AK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS-209 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 seven individuals who are designated as General supervisors, of which six of the seven are testing personnel and three of the seven are designated as technical supervisors. 2. Review of personnel competency records revealed that 3 of 3 technical supervisors, and seven of seven general supervisors, did not have annual competencies performed to assess their competency for those responsibilities as Technical supervisor or General supervisors and the additional responsibilities as delegated by the laboratory director for 2019 and 2020. 3. The laboratory manger confirmed the lack of competency assessments for Technical supervisors/General supervisors by interview on February 11, 2021 at 10:20 a.m. 4. The laboratory reports performing 284,000 patient samples annually.</p>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>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</p>

rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on observation and interview with the laboratory manager on 02/11/2021, the laboratory failed to follow established written policies and procedures for each of the following, specimen storage and preservation, conditions for specimen transportation. Findings include: 1. The laboratory had established its VTM media stability for SARS CoV-2 storage and transport to be at 2-8 degrees Celsius once inoculated or frozen at -70 degrees. 2. During the tour of the laboratory's receiving processing area, it was observed that the laboratory did not take the temperatures of the of the samples upon receipt. 3. The laboratory failed follow their established information for use, of their own VTM media by monitoring and documenting the temperatures of patient VTM SARS CoV-2 specimens for acceptability upon receipt prior to testing. 4. The laboratory manager confirmed by interview on January 11, 2021 at 5:00 p.m. the lack of monitoring and documenting specimen temperature acceptability. 5. The laboratory reports performing 210,000 SARS CoV-2 molecular tests annually. .