

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D0674508	<b>(X3) Date Survey Completed</b>  06/27/2022
<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>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the patient test reports and an interview with the technical supervisor (TS#1), the laboratory failed to include pertinent reference intervals, normal or expected values on the final test reports. Findings: 1. A review of final test reports for the following tests revealed that no normal or expected values were available on the final test reports for: a. HIV 1/2 b. VZV IgG c. Hepatitis C Virus 2. An interview conducted on June 27, 2022 at approximately 12:30 PM with TS #1 assigned to the Virology and General Immunology sections, confirmed that the final reports for all analytes do not include reference intervals, normal or expected values. 3. The laboratory reports performing approximately 72, 450 patient samples annually.</p>
<b>D5813</b>	<p>TEST REPORT CFR(s): 493.1291(g)</p> <p>The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation and an interview with the laboratory director and the technical supervisor (TS#1) it was determined that the laboratory did not have a</p>

policy or documentation of notification of results when imminent life-threatening conditions, panic or alert values are obtained. Findings: 1. A review of the Quality Assurance policy revealed that the laboratory failed to establish a policy or process to address how imminent life-threatening conditions, panic or alert values are reported and documented. 2. An interview conducted on June 27, 2022 at approximately 5:30 PM with the Laboratory Director and TS#1, confirmed that the laboratory did not have a policy to identify which results would be considered significant and require immediate notification to the authorized provider or individual. 3. The laboratory reports performing approximately 72, 450 patient samples annually.

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the

factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with the technical supervisor (TS#1) assigned to the Virology and General Immunology sections, two testing personnel did not meet the educational qualifications and training requirements to perform high complexity testing. Findings: 1. A review of diplomas and transcripts revealed that the two of ten testing personnel listed on the CMS 209 as testing personnel (TP) for Virology and General Immunology did not meet the minimum educational and training requirements to perform high complexity testing. 2. A further review of TP #1's transcripts revealed that the TP did not have a qualifying degree or the number of semester hours required to perform high complexity testing in any specialty. 3. A further review of TP #3's transcripts revealed that the individual had a Bachelor's of Arts degree and although the appropriate number of semester hours had been met, the TP did not have 3 months of documented training in Virology and General Immunology. 4. An interview conducted on June 27, 2022 at approximately 9: 10 AM with TS#1 confirmed that TP #1 and 3 did not meet the requirements to perform high complexity testing in the specialties of Virology and General Immunology.