Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0674508	01/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Alaska State Virology Laboratory	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2081	GENERAL IMMUNOLOGY CFR(s): 493.837(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on document review of College of American Pathologist (CAP) proficiency testing (PT) for immunology analytes Hepatitis B core antigen (Anti-HBc) and Hepatitis B surface antigen (HBsAg) and interview with the Technical Supervisor (TS), the laboratory failed to submit 2023 second (B) event PT results for immunology analytes. Findings include: 1. A review of CAP 2023 Event B revealed that the laboratory failed to submit the 2023 Immunology Event B PT results within the time frame specified by CAP for scoring, which resulted in unsatisfactory performance and a score of 0. Event Analyte Score 2023-B Anti-HBc 0 2023-B HBsAg 0 2. Interview with the TS confirmed on 01/10/2024 at 2:00 pm that the PT was not returned to CAP in time for scoring. 3. The laboratory reports performing 25,020 immunology tests annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on document review and interview with the laboratory director (LD), the laboratory failed to ensure Quality Assessment (QA) review of the staff competency assessment forms. Findings include: 1. Policy review of "Performing Competency Assessments for CLIA Personnel" states, "The QA officer must review the forms annually and sign/date at the top of the form." 2. A review of 17 of 17 competency Assessment forms for 2022 and 70 of 70 for 2023 had not been reviewed by the QA officer. 3. An interview with the LD confirmed on 1/10/2024 at 11:30 am that the QA officer did not review the competency assessment forms. 4. The laboratory reports performing 42,515 tests annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, document review, and interview with the Technical Supervisor (TS), the laboratory failed to ensure annual pipette calibrations were performed for the year 2023. Findings include: 1. A tour of the laboratory on 01/10/2023 at 03:20 pm Reagent Prep Room 206B, Specimen Prep Room 206C, and Specimen Prep Room 210C revealed that 14 of 14 observed pipettes had expired calibrations of October 2023. 2. A document review of the "Updated Pipette Inventory" revealed that all pipettes were due for calibration. S/N Due D0301178A 09/19/2023 C011130741 09/19 /2023 Media Prep (Room 202) S/N Due H0801028A 10/13/2023 L0507975A 10/14 /2023 C011158586 10/13/2023 Main Lab (Room 206) - Rabies S/N Due J39073D 09 /19/2023 2220209 11/29/2023 014662C 09/19/2023 Main Lab (Room 206) - Geenius S/N Due A0402643A 09/23/2023 H13848D 09/19/2023 318850 09/19/2023 O14556C 09/19/2023 Main Lab (Room 206) - Immunology S/N Due 3919809 09/19/2023 3747039 09/19/2023 O14537C 09/19/2023 G33944C 09/23/2023 Reagent Prep (Room 206B) S/N Due C011161342 10/13/2023 K0921195A 10/14/2023 D0300667A 10/13/2023 Specimen Prep (Room 206C) S/N Due K0916534A 09/19/2023 K0920398A 10/13/2023 L0936138A 10/14/2023 C011160803 10/14/2023 K0921334A 09/23/2023 C044371274 10/13/2023 Sequencing (Room 211A2) - Bench S/N Due D0301139A 09/19/2023 K0916531A 09/19/2023 C011130722 09/19/2023 C017341829 11/22/2023 3762639 09/19/2023 Sequencing (Room 211A2) - Main BSC S/N Due C011160796 09/23/2023 C044416428 11/22/2023 Sequencing Special Path (Room 211A2B) S/N Due J0901405A 09/19/2023 K0921300A 09/23/2023 C214835551 09/23/2023 Kingfisher (Room 211A3) S/N Due F0879328A 09/19/2023 C011130725 09/19/2023 B1107810A 10/13/2023 C044416153 09/23/2023 J1149125T 11/22/2023 Reagent Prep (Room 210D) S/N Due K0916511A 10/13/2023 C0303417A 10/14/2023 K0921321A 10/14/2023 J1149162T 10/14/2023 Specimen Prep (Room 210C) S/N Due C011161328 11/21/2023 H08033068 11/21/2023 L0936223A 10/14/2023 K0920166A 09/19/2023 K0916201A 09/23/2023 G0301167A 09/23/2023 C017341849 10/14/2023 C048594468 11/22/2023 Amplification Room (210B) S/N Due C011161662 11/21/2023 C0303369A 10/14

	/2023 F0300048A 11/18/2023 B1105192A 10/14/2023 3. An interview with the TS confirmed on 1/10/2024 at 4:15 pm that pipette calibrations were not performed for the year 2023. 4. The laboratory reports performing 42,515 tests annually.