Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0674508	07/23/2026
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on interviews with staff, a review of the laboratory's policies and procedures, and the manufacturer's instructions, the laboratory failed to follow the manufacturer's instructions for specimen stability and transport for patient specimens received from outside the facility. a. During an interview on 07/23/2026 at 10:14 AM, Testing Personnel #12, as listed on the CMS-209, stated that when the laboratory receives specimens, they are removed from the packing container, and the temperature is only taken if the cold packs inside are not frozen. During an interview on 07/23/2026 at 10:56 AM, the Laboratory Director confirmed that no separate studies on specimen transport stability were performed. b. A review of the laboratory's form "7.27.26 Form1 Specimen Receipt Daily Temp [temperature] Log" revealed "Frozen specimen (s): write 'Frz'; no temp. needed ...Frozen gel pack(s): write 'Frz'; not temp. needed." c. A review of the laboratory's online test directory for a sample of tests revealed: "Human Immunodeficiency Virus [HIV] ...Ship on dry ice or many frozen cold packs. Ambient temperature shipping is not recommended per reagent manufacturer guidelines. Refrigerated specimens are also not recommended due to manufacturer limitations on completing testing within 7 days (including transit time) if stored at 2-8C. Samples received warm, grossly hemolyzed, highly lipemic or turbid, or collected in other collection devices may be rejected." The temperature range was not defined for "ambient" and "warm". d. A review of the manufacturer's instructions "DiaSorin

	Liaison Murex HIV Ab [antibody]/Ag [antigen]" revealed "Specimen Collection and Preparation ...Specimens may be shipped on dry ice (frozen), on wet ice (for 2-8C [degrees Celsius]) or at room temperature (20-25C) ...Uncontrolled transport conditions (in terms of temperature and time) can cause inaccurate analytical results." The laboratory's total estimated annual test volume was 25,227.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures and an interview with General Supervisor (GS) #3, the laboratory failed to define a temperature range for specimen acceptability and rejection for 1 of 3 procedures reviewed. a. A review of the laboratory procedure "Job Aid: Handling Specimen Submission Errors in Molecular Virology" revealed "Condition Unsatisfactory Specimens ...Specimen is unsatisfactory if ...Not chilled in Transit (NCT)-NO COLD PACKS." The temperature range was not defined for "chilled". b. During an interview on 07/23/2026 at 11:27 AM GS #3, as listed on the CMS-209, confirmed a temperature range was not defined.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: I. Based on direct observation, manufacturer's instructions, lack of temperature monitoring records, and an interview with General Supervisor (GS) #3, the laboratory failed to ensure the room temperature range was consistent with manufacturer's instructions for 1 of 1 months reviewed. a. An observation on 07/23/2026 at 10:11 AM in room 210C of the laboratory revealed an EZ1 Advanced XL. b. A review of the manufacturer's instructions "EZ1 Advanced XL User Manual" revealed "Appendix A ...Operating Conditions ...Air Temperature ...15-30C [degrees Celsius]." c. The laboratory was asked to provide documentation for monitoring the room temperature. No documentation was provided. d. During an interview on 07/23/2026 at 10:11 AM, GS#3, as listed on the CMS-209, confirmed the room temperature was not monitored. II. Based on direct observation, lack of temperature monitoring records, and an interview with General Supervisor (GS) #3, the laboratory failed to define and monitor the room temperature range for 1 of 1 months reviewed. a. An observation on 07/23/2026 at 10:03 AM in room 206C of the laboratory revealed 1 bottle labeled "70% Isopropyl Alcohol ...Store at Room Temp [temperature]" and 1 bottle labeled "70% EtOH [ethanol] ... Store at Room Temp". b. The laboratory was asked to provide documentation for monitoring the room temperature. No documentation was provided. c. During an interview on 07/23/2026 at 10:03 AM, GS#3, as listed on the CMS-209, confirmed the room temperature was not monitored.