Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2283229	09/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Alyeska Vascular Surgery, Llc	2480 S Woodworth Loop, Ste 120, Palmer, 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
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 procedure review and an interview with the Technical Consultant (TC), the laboratory failed to ensure the procedure manual for the Abbott i-STAT Chem 8+ chemistry panel and activated clotting time (ACT) had all the applicable requirements, including specimen labeling, processing, entering results in the patient record, and reporting results, including panic or alert values. Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory uses the manufacturer's procedures for i-STAT tests. 2. A review of manufacturer's procedures for i-STAT

	Chem 8+ panel and ACT were missing laboratory-specific instructions for specimen labeling and processing, entering results in the patient record, and reporting results. 3. An on-site interview with TC on 9/5/25 at 11:00 AM confirmed these findings. 4. The laboratory reports performing 1,500 tests for Chem 8+ panel and ACT annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following: This STANDARD is not met as evidenced by: Based on observations, record review and interview with the Technical Consultant (TC), the laboratory failed to perform function checks at the frequency specified in the manufacturer's instructions for three of three environmental sensors used to monitor refrigerator temperature, room temperature and humidity. Findings include: 1. Observation on 9/5/25 at 10:30 AM of the room temperature thermometer (Fisherbrand S66279, SN 230190709), where Abbott i-STAT chemistry, hemotology, and serum Hcg testing is performed, showed calibration due 3/21/2025. 2. Observation on 9/5/25 at 10:30 AM of the refrigerator thermometer (SN 12566), where i-STAT reagents and quality control samples are stored, has "RC due 07/2025". 3. Observation on 9/5/25 at 10:30 AM of the electronic refrigerator temperature sensor (CX403, SN 21385720) showed there was no notation of in-use date or expiration date. 4. Review of the certificate of calibration for all three thermometers revealed calibration was overdue (room temperature 3/21/2025, refrigerator 7/2025, electronic refrigerator 9/27/24). 5. In an interview with the TC 9/5/25 at 11:00 AM confirmed the findings. 6. The laboratory reports 1,500 tests annually.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on patient result review and interview with the Technical Consultant (TC), the laboratory failed to ensure the units of measure for creatinine and hemoglobin displayed on the Abbott i-STAT correlate with the units of measure programmed in the electronic charting program (OBM), and the significant digits entered in OBM for potassium are displayed as entered. Findings include: 1. During a review of a patient results reported on 9/4/2025 revealed: a. The units of measure for creatinine are

	displayed as mg/dL on the i-STAT and reported as mcL in the electronic information system (OBM). b. The units of measure for hemoglobin were displayed as g/dL on the i-STAT and reported as mcL in the electronic information system (OBM). c. A potassium concentration was displayed as 4.0 mmol/L on the i-STAT and displayed as 4 mmol/L in the electronic information system (OBM). 2. An on-site interview with TC on 9/5/2025 at 12:00 PM confirmed these findings. 3. The laboratory reports performing approximately 1,500 tests annually.