Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0640776	07/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Orthoalaska	4100 Lake Otis Parkway Suite 306, Anchorage, 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 direct observation, a review of the laboratory's policies, and manufacturers' instructions and an interview with the Technical Consultant (TC), the laboratory failed to follow the manufacturer's instructions for specimen stability and transport for 19 of 19 bags of specimens received from outside the facility. Findings Include: a. An observation on 07/21/2026 at 11:54 AM in the laboratory revealed 19 specimen bags packed in a soft-sided cooler with four ice packs that were cool to the touch. The specimens were accessioned into the laboratory. No specimen temperature was documented. A sample of specimens and tests received included: Control number PRO1679492; Tests: Triglyceride Control number PRO1680079; Tests: Aspartate Aminotransferase (AST) b. A review of the laboratory policy "Othoalaska/PCA In-House laboratory Tests Menu" revealed Triglyceride and AST specimen stability was listed as "7 days RF [refrigerate]". The refrigerated temperature range was not defined. c. A review of the manufacturer's package insert "Architect Triglyceride", revised June 2018, revealed "Specimen Storage ... Temperature/ Maximum Storage: 20 to 25C [degrees Celsius]/2 days 2 to 8C/7 days" d. A review of the manufacturer's package insert "Architect Aspartate Aminotransferase 2", revised July 2021, revealed "Specimen Storage ... Temperature/ Maximum Storage: Room Temperature (20 to

	25C)/4 days 2 to 8C/7 days" e. During an interview on 07/21/2026 at 11:11 AM and 11:54 AM, the TC confirmed specimen temperatures are not taken or documented by the laboratory, and the range is not defined.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control (QC) records, absence of documented corrective action, and an interview with the Technical Consultant (TC), the laboratory failed to evaluate 6 of 6 patient test results back to the last acceptable QC when Uric Acid (UA) QC exceeded the laboratory's acceptable limits and test system adjustments were made. Findings Include: a. A review of the "Chemistry and Immunoassay Quality Control Review and Troubleshooting Log" revealed on 05/27 /2026, UA level 3 QC exceeded the laboratory's acceptable limits. The QC was repeated and repoured; the reagent pack was recalibrated, and the repeat QC was in range. b. The laboratory was asked to provide documentation of corrective action (evaluation of patient results) since the last acceptable QC on 05/26/2026 for the following patient UA results: Identification number: PRO1654402, PRO1654614, PRO1654626, PRO1654603, PRO1654454, and PRO1654507 No documentation was provided. c. During an interview on 07/21/2026 at 11:28 AM, the TC, as listed on the CMS-209, confirmed these findings.