

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D0943068	<b>(X3) Date Survey Completed</b>  08/08/2025
<b>Name of Provider or Supplier</b>  Orthoalaska	<b>Street Address, City, State</b>  17101 Snowmobile Lane Ste 102, Eagle River, 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>D5431</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(2)</p> <p>(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:</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review, and an interview with Technical Consultant 1 (TC1), the laboratory failed to verify the accuracy of two of two thermometers, one used to monitor the refrigerator where erythrocyte sedimentation rate (ESR) controls and reagents are stored, and the other to monitor the room temperature and humidity where patient testing occurs. Findings include: 1. Observation on 8/8/2025 at 12:00 PM, showed the refrigerator thermometer (SN 221838337) did not have a date in use or calibration date indicated on the thermometer. 2. Observation on 8/8/2025 at 12:00 PM, showed the digital thermometer/humidity monitor (SN 170012660) used in the laboratory had a calibration expiry date of 1/7/2019. 3. A request was made to review the thermometer calibration certificate or verification of accuracy, and documentation could not be provided. 4. An interview with TC1 on 8/9/2025 at 1:00 PM confirmed these findings. 5. The laboratory reports performing approximately 150 ESR tests annually.</p>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient</p>

identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on reviews of the Erythrocyte Sedimentation Rate (ESR) procedure, patient test results, laboratory information system (LIS) reference ranges, and an interview with Technical Consultant 1 (TC1), the laboratory failed to ensure the reference ranges for ESR were accurately reported for patients over 50 years of age. Findings include: 1. The Excyte Mini automated ESR analyzer procedure, effective 9/19/2016, specifies a reference range of 0-15 mm/hour for males and 0-20 mm/hour for females. 2. A random review of four patient test results revealed the reference range for patients over 50 years of age did not match the reference ranges stated in the procedure. The reference range for patient #538177, a female over 50 years of age, was reported as 0-30 mm/hour. 3. A review of the Laboratory Information System (LIS) revealed separate programmed reference ranges for males (0-20 mm/hour) and females (0-30 mm/hour) over 50 years of age did not match the reference ranges in the ESR procedure. 4. An interview with TC1 on 8/9/2025 at 1:00 PM confirmed these findings. 5. The laboratory reports performing approximately 150 ESRs annually. 6. This deficiency was corrected on-site on 8/9/2025 at 1:15 PM.