

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D1090167	<b>(X3) Date Survey Completed</b>  05/31/2023
<b>Name of Provider or Supplier</b>  Lifemed Alaska Llc	<b>Street Address, City, State</b>  6320 S Airpark Place, Anchorage, 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>D5555</b>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)</p> <p>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of refrigerator temperature logs and an interview with the laboratory director, the laboratory failed to regularly perform and document alarm checks verifying an audible alarm was activated at the appropriate temperature(s) in refrigerators where blood products are stored. Findings include: 1. A request was made to review documentation of alarm checks when the refrigerator temperature falls outside the acceptable range, and documentation could not be provided. 2. An interview conducted on May 31, 2023 at approximately 3:00 PM, the laboratory director confirmed the laboratory did not have written documentation or evidence of alarm checks. 3. The laboratory reports storing packed red blood cells in refrigerators at the Anchorage, Fairbanks, Palmer, Soldotna, Dutch Harbor and Juneau bases.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on a review of the Individualized Quality Control Plan (IQCP), quality assessment records, and interview with the laboratory director, the laboratory failed to establish and follow a quality assessment plan for the ongoing monitoring of the effectiveness of the IQCP for the Abbott i-STAT CG8+ cartridges. Findings include:  
1. A request was made to review the IQCP for the Abbott i-STAT CG8+ cartridges and the quality assessment part of the plan could not be provided. 2. An interview conducted on May 31, 2023 at approximately 3:00 PM, the laboratory director confirmed the laboratory did not have written documentation or evidence of the quality assessment plan as part of the IQCP. 3. The laboratory reports performing approximately 5,100 i-STAT tests annually.