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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 02D1090167 | (X3) Date Survey Completed 04/11/2025 |
| Name of Provider or Supplier Lifemed Alaska Llc | Street Address, City, State 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. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D5781 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</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 document the corrective actions taken when the refrigerator temperatures where un-crossmatched blood and i-STAT CG8+ cartridges are stored, were outside the acceptable criteria for 7 out of 7 events from April 2024 to April 2025. Findings include: 1. Review of refrigerator temperature logs revealed the temperature exceeded the acceptable range of 1 to 6 degrees C without corrective action documented. a. Dutch Harbor refrigerator 3/11/25 from 07:43 to 09:19 b. Dutch Harbor refrigerator 3/11/25 from 13:07 to 13:57 c. Dutch Harbor refrigerator 3/11/25 from 13:32 to 14:48 d. Dutch Harbor refrigerator 4/3/25 from 14:22 to 14:34 e. Dutch Harbor refrigerator 4/6/25 from 14:47 to 14:58 f. Wolf Lake refrigerator 11/23/24 from 07:53 to 09:18 g. Wolf Lake refrigerator 10/26/24 from 14:52 to 16:29 2. The laboratory reports storing reagents to perform approximately 4,000 chemistry tests and 575 hematology tests annually, and storing units of packed red blood cells for emergency transfusions in the refrigerators. 3. During an on-site</p> |

interview on 4/11/2025 at 1:30 PM, the laboratory director confirmed there was no corrective action documented when the temperatures were outside the acceptable range.