

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2028442	(X3) Date Survey Completed 09/11/2025
Name of Provider or Supplier Guardian Flight, Llc	Street Address, City, State 3474 Old International Airport Road, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Guardian Flight Point of Care Policy and Procedures implemented on June 1, 2011 and an interview with the Technical Consultant (TC1), the laboratory failed to ensure procedural changes for the Abbott i-STAT including current tests offered, specimen collection and processing, quality control, calibration verification, and current critical values were updated, approved, signed and dated by the laboratory director. Findings include: 1. A review of the Guardian Flight Point of Care Policy and Procedures for i-STAT testing on 9/11/25 at 2:00 PM revealed the following: a. The reagent section on page 22 indicated use of the EG8+ cartridges and the reference range section on page 34 included a reference range for ACT cartridges; the laboratory is currently using CG8+ and Chem8+ cartridges. b. The procedure references collecting capillary specimens; the laboratory collects venous and arterial samples. c. The electronic control frequency, type of control material used, and the frequency of liquid control does not match their current practices. d. The calibration verification (Cal/Ver) section on page 5 states cal/vers will be performed with new lots, after major maintenance, and every 6 months following the CLEW updates; the laboratory does not currently perform calibration verifications. e. The critical values listed on page 32 for sodium, potassium, BUN, hemoglobin, hematocrit, pH, PCO2, TCO2, HCO3, base excess, and anion gap do not match the i-STAT Results worksheet transported with the patient and given to the receiving facility. 2. An on-site interview with TC1 on 9/11/2025 at 3:30 PM in Anchorage confirmed the procedure did not match current practices. 3. The laboratory reports performing approximately 1,280 tests annually.</p>

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observations, lack of documentation, an interview with the Technical Consultant (TC1), and a review of the Guardian Flight Point of Care Policy and Procedures implemented on June 1, 2011, the laboratory failed to monitor and document the room temperature at seven (7) of seven (7) sites to ensure the manufacture instructions are followed where Abbott i-STAT cartridges are stored. Findings include: 1. Observations in the laboratory supply storage area on 9/11/25 at 11:00 AM in Anchorage revealed the laboratory stores i-STAT cartridges at room temperature until the expiration date but there is no documentation of room temperatures. 2. An on-site interview with the TC1 on 9/11/25 at 11:00 AM in Anchorage confirmed that room temperatures are not monitored or recorded for any of the sites where cartridges are stored (Anchorage, Deadhorse, Fairbanks, Juneau, Kenai, Ketchikan, and Sitka bases). 3. Review of the laboratory 's i-STAT Testing procedure 9/11/25 at 2:00 PM revealed "cartridges may be stored at room temperature (18 - 30 C)". 4. Review of the i-STAT CG8+ Cartridge procedure reveals room temperature storage conditions are 18 - 30 C. 5. The laboratory reports performing approximately 1,280 tests annually.