Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2028442	(X3) Date Survey Completed 12/03/2021
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control log sheets from May to November 2021 and interview with the Technical Consultant, the laboratory did not test, at a minimum 2 levels of external quality control (QC) material to monitor the accuracy and precision of the Abbott i-STAT Chem-8+ cartridges each day patient samples were tested. Findings include: 1. Quality control logs for the i-STATs for May through November of 2021 showed that external quality control was performed with each lot or shipment of cartridges occurring on 5/6/21, 6/4/21, 7/16/21, 9/1/21, 9/29/21, and 11/19/21. 2. The laboratory uses approximately 140 i-STAT Chem 8+ cartridges annually, resulting in approximately 1120 individual patient tests. 3. The Technical Consultant confirmed these finding on 12/3/21 at 3:00 pm.