Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2028442	10/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Guardian Flight, Llc	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 a review of quality control records and staff interview, the laboratory did not test, at a minimum, two levels of external quality control material to monitor the accuracy and precision of the Abbott i-STAT EC8+ cartridges each day of patient testing. 1. The i-STAT procedure states external quality controls (QC) will be performed with each new lot and or shipment of cartridges. 2. A review of the i-STAT quality control logs for 2018 and 2019, revealed the laboratory had documented 3 levels of external quality control for a shipment of cartridges on 10/11/19. 3. Documentation was missing for all other quality control tests on the i- i-STAT CG8+ cartridges. 4. The laboratory performs approximately 825 patient tests on the i- i-STAT annually. 5. The testing coordinator confirmed these finding on 10/17/19 at 15: 45 pm.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

	of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and staff interview, the laboratory did not have copies of diplomas or transcripts for testing personnel. Findings: 1. The laboratory had 31 new testing personnel since the previous survey on 8/22/17. 10 of the 31 were missing diplomas or transcripts to verify education. 2. The human resources department was responsible for obtaining the diploma, transcript, or equivalent for newly hired testing personnel. 3. The testing coordinator confirmed these findings on 10/17/19 at 15:45 pm.