Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2259643	03/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Cardiovascular Institute At Deltona	1615 Dr Martin Luther King Jr Blvd, Ste A, Deltona, FL	

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
D0000	At the time of the announced, on-site recertification survey, Advanced Cardiovascular Institute at Deltona, was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 record review and staff interview, the laboratory failed to document 2 levels of external quality control (QC) on the ITC Hemochron Jr Signature Micros for the analyte ACT (Activated Clotting Time) in December 2023. Findings include: Review of QC records for the ITC Hemochron Jr Signature Micros showed that the abnormal external monthly QC was not documented in December 2023. The laboratory procedure titled "Activated Clotting Time Low Range Testing" states "Frequency of Liquid QC - Each lot of the Hemochron Jr cuvettes should be validated for performance using 2 levels of LQC: When a new shipment is received AND Once per 30 calendar days thereafter." During an interview on 3/5/24 at 10:20am, the Director of Nursing confirmed that the abnormal external QC for December 2023 was not documented.