

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2265914	(X3) Date Survey Completed 03/13/2024
Name of Provider or Supplier Virginia Cardiovascular Specialists Heart	Street Address, City, State 8007 Discovery Dr, Richmond, VA	
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	An announced CLIA Initial survey was conducted at the Virginia Cardiovascular Specialists Heart and Vascular Center on 03/13/24 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's initial verification and Individualized Quality Control Plan (IQCP) documentation, quality control (QC) records, daily patient test logs, lack of documentation, and an interview, the laboratory failed to perform at least two levels of QC materials each day of patient testing for the non-waived Abbott i-STAT Celite Activated Clotting Time (ACT) analyte/cartridge for six of six days reviewed from 01/09/24 through 02/27/24 and reporting a total of 8 patients. Findings include: 1. Review of the laboratory's initial verification documentation the for the i-STAT Celite ACT analyte/cartridge revealed an IQCP policy reviewed and approved by the laboratory director on 02/28/24. 2. Review QC records and daily patient testing logs revealed a lack of documentation of at least two levels of QC materials assayed for the following dates (prior to the IQCP approval by the laboratory director): 01/09/24- 2 patients reported, 01/16/24- 1 patient reported, 02/12/24- 1 patient reported, 02/13/24- 2 patient reported, 02/21/24- 1 patient reported and 02/27/24- 1 patient reported. 3. An exit interview with the technical consultant on 03/13/24 at 10:45 AM confirmed the findings.</p>