Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2265914	10/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Cardiovascular Specialists Heart	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 recertification survey was conducted at Virginia Cardiovascular Specialists on October 16, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Virginia Cardiovascular Specialists was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation and interview, the laboratory failed to establish and follow a policy for one (1) of 1 Technical Consultant (TC) competency assessment from April 2024 through the date of the survey, 10/16/25. The findings include: 1. Review of the CMS 209 revealed the laboratory director (LD) identified one Technical Consultant (TC) for the specialties of Hematology and Chemistry, TC #1. (See attached personnel code sheet.) 2. Review of the laboratory's personnel records from April 2024 through 10/16/25 revealed no competency assessment documented for TC #1. The surveyor requested to review the competency assessment of duties performed as a technical consultant. The TC stated at approximately 10 AM on 10/16/25 that there was no documentation available for review. 3. Review of the laboratory policy and procedure manual revealed the lack of a policy outlining the performance and documentation of TC competency assessment. 4. In an exit interview with the TC on October 16, 2025 at 11:25 AM, the above findings were confirmed.

D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing (PT) records, laboratory policy and procedure manual, lack of documentation, and interviews, the laboratory failed to establish a written policy to test, submit, and assess results of proficiency samples at the time of the survey on 10/16/25. The findings include: 1. Review of the laboratory's PT records revealed the laboratory participates in American Pathology Institute (API) proficiency testing as customer number 85063 for the Chemistry Core and Hematology modules. 2. Review of the laboratory's policy and procedure manual revealed the lack of a written policy for testing proficiency samples, submitting PT results to API, and assessing returned results. When asked on 10/16/25 at 11:15 AM if the lab had a PT policy, the technical consultant (TC) stated that there was none. 3. In an exit interview with the TC on 10/16/25 at 11:45 AM, the findings were confirmed.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's survey Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form (CMS 116), Abbott i-STAT patient result reports, lack of documentation and interviews, the laboratory's Activated Clotting Time (ACT) and Chemistry (Chem 8+) patient reports failed to include reference intervals for twenty one (21) of 21 patient test reports reviewed. The findings include: 1. Pre-survey review of the submitted CMS 116 revealed the laboratory utilizes the Abbott i-STAT with Chem 8+(analytes: Sodium, potassium, chloride, Ionized calcium, total Carbon dioxide, glucose, blood urea nitrogen (BUN), creatinine, hemoglobin, hematorcrit) and ACT cartridges for patient testing. 2. Review of the patient logs from September 2025 through the date of the survey, 10/16/25, revealed individual patient worksheets that contained a patient label along with the corresponding i-STAT result print out. Twenty one (21) of 21 Chem 8+ and ACT patient reports reviewed lacked reference intervals for the above listed tests. When asked about reference range availability at 10:41 AM on 10/16/25, the Technical Consultant (TC) stated that the ranges were not in the Electronic Medical Record (EMR). 3. In an exit interview with the TC on October 16, 2025 at 11:25 AM, the findings were confirmed.