

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0990565	(X3) Date Survey Completed 07/07/2026
Name of Provider or Supplier Hanover Cardiac Asc Llc DbA Virginia Cardiac	Street Address, City, State 8160 Pleasant Grove Road, Suite 100, Mechanicsville, 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 Hanover Cardiac ASC LLC dba Virginia Cardiac on July 7, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Hanover Cardiac ASC LLC dba Virginia Cardiac was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing (PT) records, policies and procedures, and interview, the laboratory failed to retain PT attestation sheets signed by the Laboratory Director (LD) or designee for three (3) of eleven (11) PT events reviewed. Findings include: 1. The laboratory participates in Hematology (HEME) and Chemistry (CHEM) PT modules with American Proficiency Institute (API) as customer number 82401. Review of the laboratory's PT records for the HEME and CHEM 3rd events in 2024, all events in 2025, the 1st events in 2026, and the 2nd 2026 CHEM event (a total of 11 events) revealed a lack of director or designee signature of attestation on the following 3 PT events documentation: 2024 CHEM 3rd event, 2026 HEME 1st event, and 2026 CHEM 2nd event. 2. Review of laboratory's Quality Assurance policy revealed section 15 titled Proficiency Testing includes "attestation statements are signed and retained." 3. In an interview at 12:14 pm on 7/7 /26 with the LD and Technical Consultant, the findings above were confirmed.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing (PT) records, policies and procedures, and interviews, the laboratory failed to document review of PT result evaluations as indicated by Laboratory Director (LD) or designee signature for three (3) of eleven (11) PT events reviewed. Findings include: 1. The laboratory participates in Hematology (HEME) and Chemistry (CHEM) PT modules with American Proficiency Institute (API) as customer number 82401. Review of the laboratory's PT records for the HEME and CHEM 3rd events in 2024, all events in 2025, the 1st events in 2026, and the 2nd 2026 CHEM event (a total of 11 events) revealed a lack of director or designee signature indicating review of results on the following 3 PT events result evaluations: 2024 CHEM 3rd event, 2026 HEME 1st event, and 2026 CHEM 2nd event. 2. Review of laboratory's General Lab policy manual revealed section 12 titled Proficiency Testing includes "Scores below 100% should prompt investigation to identify the cause." The laboratory's Quality Assurance policy section 15 Proficiency Testing includes "scores below 100% investigated with corrective action, verify corrective action was documented for any scores below 100%". The lab policies and procedures lacked who (director or designee) was to review PT results. 3. When asked at 12:06 pm on 7/7/26 about a current policy and procedure that included designation of PT result review, the Technical Consultant (TC) confirmed that there was no Designee policy. 4. In an interview at 12:14 pm on 7/7/26 with the LD and TC, the findings above were confirmed.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on a review of the survey Centers for Medicare and Medicaid Services Application for Certification Form (CMS116), laboratory proficiency testing (PT) documentation, Method verification, Quality Control (QC) records, Patient results, lab tour and interview, it was determined that the laboratory failed to establish and follow a policy to perform twice annual accuracy checks for the i-STAT analytes Lactate and oxygen saturation (sO2) in calendar year 2025 to the date of survey, 7/7/26. Findings include: 1. Review of the survey CMS116 revealed the lab utilizes the Abbott i-STAT system with CG4+ cartridges for patient testing that includes the analytes Lactate and sO2. 2. Review of the laboratory's 2025 and 2026 American Proficiency Institute (API) PT records revealed the lab participates in API's HEME and CHEM modules for analytes Activated Clotting Time, Sodium, Potassium, Chloride, ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, calculated Hb, and Anion Gap. The 2025 and 2026 PT records lacked PT testing for lactate and sO2. 3. Review of the laboratory's iStat Method Verification Report (with instrument raw data from 2025) included analytes Lactate & sO2. 4. Review of the available 2025 and 2026 QC printouts and patient results revealed patient testing utilizing the CG4 cartridge started

in July of 2025. 5. During a lab tour at 12:02 pm on 7/7/26, it was noted that the refrigerator contained 2 boxes of iStat CG4 cartridges. 6. In an interview at 12:14 pm on 7/7/26 with the Laboratory Director and Technical Consultant, the findings above were confirmed.