

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2238358	(X3) Date Survey Completed 01/14/2026
Name of Provider or Supplier Bay Area Heart Surgery Center	Street Address, City, State 3600 66th St N, Saint Petersburg, 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	An announced CLIA recertification survey was conducted at Bay Area Heart Surgery Center on 01/14/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to identify, via monthly quality assessment reviews, an electronic simulator check (internal control check) was not performed and documented for one (20th) of four days (13th, 20th, 26th and 29th) patient testing was performed in August 2024 for the test - Activated Clotting Factor (ACT) in the specialty of Hematology. Findings include: 1. The Laboratory Specimen Log for 08/2024 was reviewed. ACT patient tests were performed on the 13th, 20th, 26th, and 29th. 2. The August 2024 Maintenance and System Check Log, was reviewed. The form was signed by the Laboratory Director on 08/31/2024. The electronic simulator check was not documented as completed and acceptable on 08/20/2024. The form indicated no patient testing was performed. 3. The Laboratory Monthly Quality Assurance and QC review form was reviewed for 08 /2024. The form was signed by the Laboratory Director on 08/31/2024. The section titled "Preventative maintenance and systems checks completed and documented" was filled out indicating the electronic simulator checks were completed and documented each day patient testing was performed. 4. Electronic correspondence (interview) dated 01/14/2026 from the Laboratory Director, confirmed the above data.</p>