

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2238358	(X3) Date Survey Completed 07/12/2022
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 07/12/22. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6033 - 42 CFR 493.1409: Laboratories performing moderate complexity testing; technical consultant
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have a qualified Technical Consultant in the Specialty of Hematology and Subspecialty of Routine Chemistry from 04/26/22 to 07/12/22 with an annual estimated test volume of 1380 (See D6034).</p>
D6034	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the laboratory failed to have a qualified Technical Consultant to provide technical oversight of the testing process which commenced on 04/26/22 to 07/12/22. Findings Included: Record review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 07/08/2022 revealed the Laboratory Director also functioned as the Technical Consultant for moderate complexity testing in the Specialty of Hematology and Subspecialty of Routine Chemistry. Review of the CMS-116, Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed by the Laboratory Director on 7/12/22 revealed the estimated annual test volume for Hematology was 1248, and Routine Chemistry was 132 for a total estimated test volume of 1380. Review of the Laboratory Director's personnel records revealed he became the Laboratory Director on 10/04/21. Review of the Laboratory Director's Curriculum Vitae (CV) and additional education/training records revealed no evidence of 1 year of laboratory training. Record review of the laboratory's policy titled "LAB 101 Laboratory Director's Responsibilities" revealed "The Laboratory Director, if qualified, may perform the duties of the technical consultant... or delegate these responsibilities to personnel meeting the qualification of 493.1409, 493.1415, and 493.1421. On 07/12/22 at 10:25 AM, the Surgery Center Director stated she did not know that the Laboratory Director needed 1 year of laboratory training to become the Technical Consultant. She did not know additional training was required beyond the 20 hour Continuing Medical Education (CME) course required to be qualified as the Laboratory Director.