

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2166119	(X3) Date Survey Completed 10/12/2023
Name of Provider or Supplier Heart Center Cardiology Pc, The	Street Address, City, State 121 N 20th Street Ste 20b, Opelika, AL	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Chemistry Quality Control (QC) records, the ISTAT Individualized Quality Control Plan (IQCP), and an interview with Testing Personnel #2, the Laboratory failed to ensure testing personnel performed the ISTAT QC every 30 days as per the IQCP. The surveyor noted one out of ten months in 2023 when QC was not performed as required by the IQCP. The findings include: 1. A review of the ISTAT Chemistry IQCP revealed, "Liquid QC is performed monthly on each lot of in-use cartridges..." 2. A review of the ISTAT records revealed QC was performed on 6/28/2023 and 8/1/2023. No evidence of QC performed in July 2023 was available for review. 3. During an interview on October 12, 2023, at 1:00 PM, Testing Personnel #2 confirmed the above findings.</p>