Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2166119	11/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Heart Center Cardiology Pc, The	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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the I-STAT liquid Quality Control (QC) records, and an interview with the Technical Consultant, the laboratory used expired QC reagent on the I-STAT Chemistry analyzer. The surveyor noted the laboratory utilized expired QC for 30 days of patient testing reviewed in 2024 and 2025. The findings include: 1. A review of the I-STAT liquid QC records revealed the following: a) I-STAT QC level 1 lot #301163 and level 2 #321163 expired 7/31/2024 and performed on 7/11 /2024 and 8/26/2024, a new lot of QC not expired was performed on 9/4/2024. I-STAT QC is good for 30 days, during the period of 8/12/2024 through 9/3/2024 (22 days) there were 26 patients that were affected. b) I-STAT QC level 1 lot #301174 and level 2 lot #321174 expired on 6/30/2025 and performed on 7/7/2025, a new lot of QC not expired was performed on 7/16/2025. I-STAT QC is good for 30 days, during the period of 7/7/2025 through 7/15/2025 (8 days) there were 27 patients affected. 2. A further review of the I-STAT Liquid QC Procedure revealed, "Be sure cartridges and quality controls are in-date." 3. During an interview on 11/19/2025, at 12:40 PM, the TC confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable

	limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the I-STAT calibration verification (C-V) records, policy and procedures, and an interview with the Technical Consultant, the laboratory failed to ensure C-V was performed and documented on the I-STAT Chemistry analyzer as per the laboratory policy. This was noted for one of two C-V's missed in 2025. The findings include: 1. A review of the C-V records for the I-STAT Chemistry analyzer revealed the I-STAT was calibrated 12/26/2024 and then eleven months later on 11/11 /2025. There was no evidence of C-V documentation for the first half of 2025. 2. A further review of the I-STAT policy revealed, "A Calibration Verification set is used to verify the calibration or recalibration of I-STAT cartridges/analyzers...Calibration is performed every 6 months...". 3. During an interview on 11/19/2025 at 1:20 PM, the TC confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a review of the I-STAT QC (Quality Control) records, the Liquid QC Procedure, and an interview with the Technical Consultant (TC), the Laboratory failed to ensure testing personnel performed the I-STAT QC monthly as per the procedure. The surveyor noted two out of 26 months reviewed in 2023 through 2025 when QC was not performed as required by the laboratory's procedure. The findings include: 1. A review of the I-STAT records revealed the laboratory exceeded monthly requirements for liquid QC, as follows: a) May 2024 missed; 6 patients affected. b) April 2025 missed; 29 patients affected. 2. A review of the I-STAT Liquid QC Procedure revealed, "Liquid QC is performed monthly..." 3. During an interview on 11 /19/2025, at 12:40 PM, the TC confirmed the above findings.