Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2003635	12/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Heart Care Cfl Pllc	3822 S Washington Ave, Titusville, 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	A recertification survey was conducted on 12/17/20. Heart Care CFL PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified of the Immediate Jeopardy at 3:40 PM on 12 /17/20. The laboratory failed to perform two levels of quality controls at least daily on the days patient specimens were tested on the Abbott i-Stat instrument. The laboratory was unable to provide documentation of the performance of the calibration on the Abbott i-Stat instrument at least once every 6 months. The laboratory was unable to provide documentation of the initial validation of the Abbott i-Stat instrument. (D5400) The following Conditions were not met: D2000 - 493.801 Enrollment and Testing of Samples D5400 - 493.1250 Analytic Systems D6000 - 493.1403 Moderate Complexity Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in proficiency testing with an approved proficiency testing (PT) program for chemistry analytes in 2020. Findings: Review of the of American Proficiency Institute PT records showed there was not any documentation of proficiency testing performed on the analytes run

	on the Abbott i-Stat instrument for the Chem 8+ cartridges in 2020. The Chem 8+ i-Stat cartridges that included the following chemistry analytes: sodium, potassium, chloride, calcium, blood urea- nitrogen, total carbon dioxide, creatinine, hematocrit, anion gap, and hemoglobin. During an interview on 12/17/20 at 11:19 AM, Testing Personnel A stated they were not enrolled in proficiency testing for the Chem 8+ analytes in 2020. On 12/17/20 at 2:25 PM, Testing Personnel A stated the laboratory performed Chem 8+ tests on 76 patients from 1/1/20 to 12/17/20.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain instrument printouts of the patient test results from the Abbott i-Stat instrument for 2 (#1, #2) out of 5 (#1, #2, #3, #4, #5) patients. Findings: Review of the patients' (#1, #2) procedure notes showed that a copy of the instrument printout was not included in the documentation from the patients' electronic records. Review of the Quality Assessment Monthly Chart Check showed three patients (#3, #4, #5) instrument printouts were attached to the monthly chart check log. No other instrument printouts were noted. The laboratory performed Activated Clotting Time (ACT) and Chem 8+ testing on the Abbott i-Stat instrument. The Chem 8+ i-Stat cartridges included the following chemistry analytes: sodium, potassium, chloride, calcium, blood urea nitrogen, total carbon dioxide, creatinine, hematocrit, anion gap, and hemoglobin. The laboratory performed Chem 8+ testing on 76 patient and ACT testing on 15 patients from 1/1/20 to 12/17/20. During an interview on 12/17/20 at 3:00 PM, Testing Personnel A stated that they did not save all the printouts for all their patients.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5421. Based on record review and interview, the laboratory did not provide documentation of the validations of the Abbott i-Stat instrument. Cross Reference D5439. Based on record review and interview, the laboratory did not provide documentation of the performance of the calibration on the Abbott i-Stat instrument at least once every 6 months. Cross

	Reference D5447. Based on record review and interview, the laboratory failed to perform two levels of quality controls at least daily on the days patient specimens were tested on the Abbott i-Stat instrument.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory was unable to provide documentation of validations of the Abbott i-Stat instrument. Findings: Review of the laboratory's quality control documentation showed the laboratory did not have documentation available at the time of the survey for the validations on the Abbott i-Stat instrument. The laboratory performed Activated Clotting Time (ACT) and Chem 8+ testing. The Chem 8+ i-Stat cartridges included the following chemistry analytes: sodium, potassium, chloride, calcium, blood urea nitrogen, total carbon dioxide, creatinine, hematocrit, anion gap, and hemoglobin. During an interview on 12/17/20 at 1:10 PM, Testing Personnel A stated she did not know where the documentation on the validation of the i-Stat instrument was located. On 12/17/20 at 2:25 PM, Testing Personnel A stated the laboratory performed ACT tests on 15 patients and Chem 8+ tests on 76 patients from 1/1/20 to 12/17/20. On 12/17/20 at 2:50 PM, Testing Personnel A said the laboratory purchased the i-Stat instrument on 1/17/14.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 record review and interview, the laboratory failed to provide documentation of the performance of the calibration on the Abbott i-Stat instrument at least once every 6 months. Findings: Review of the laboratory's quality control documents showed the laboratory did not have documentation of the calibration on the Abbott i-Stat instrument. The laboratory performed Activated Clotting Time (ACT) and Chem 8+ testing. The Chem 8+ i-Stat cartridges included the following chemistry analytes: sodium, potassium, chloride, calcium, blood urea nitrogen, total carbon dioxide, creatinine, hematocrit, anion gap, and hemoglobin. During an interview on 12/17/20 at 12:51 PM, Testing Personnel A stated calibrations on the i-Stat were not performed. On 12/17/20 at 2:25 PM, Testing Personnel A said the laboratory performed ACT tests on 15 patients and Chem 8+ tests on 76 patients from 1/1/20 to 12/17/20. On 12 /17/20 at 2:50 PM, Testing Personnel A stated the laboratory purchased the i-Stat instrument on 1/17/14.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform two levels of quality controls at least daily on days when patient specimens were tested on the Abbott i-Stat instrument. Findings: Review of the laboratory's quality control records for the Abbott i-Stat instrument showed one level of liquid controls was run once a month for the Chem 8+ cartridge from 2/19/20 to 12/17/20 and Activate Clotting Time cartridge from 12/17/18 to 12/17/20. The Chem 8+ cartridges included the following chemistry analytes: sodium, potassium, chloride, calcium, blood urea nitrogen, total carbon dioxide, creatinine, hematocrit, anion gap, and hemoglobin. During an interview on 12/17/20 at 12:21 PM, Testing Personnel A stated the laboratory performed only one level of control once per month.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by:

	Based on record review and interview, the procedure notes failed to provide all the required information for laboratory test reports for 2 of 2 patients, (#1, #2). Findings: The laboratory performed Activated Clotting Time (ACT) and Chem 8+ testing on the Abbott i-Stat instrument. The Chem 8+ i-Stat cartridge included the following chemistry analytes: sodium, potassium, chloride, calcium, blood urea nitrogen, total carbon dioxide, creatinine, hematocrit, anion gap, and hemoglobin. 1. Review of the procedure notes showed the full address of the laboratory was not included in the procedure notes for 2 out of 2 (#1, #2) patients. The procedure notes showed the city, state, and zip code of the laboratory were not listed. 2. Review of the procedure notes showed the units of measurements for the ACT and Chem 8+ tests were not included in the procedure notes for 2 out of 2 (#1, #2) patients. 3. Review of the procedure notes showed the reference ranges (normal values) for the ACT and Chem 8+ tests were not included in the procedure notes for 2 out of 2 (#1, #2) patients.. During an interview on 12/17/20 at 3:00 PM, Testing Personnel A stated the procedure notes that were given to patients did not contain the full address, units of measurements and the normal values.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference D6007: Based on record review and interview, the Laboratory Director failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance including analytic and post analytical phases of testing. Cross Reference D6015: Based on record review and interview, the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing (PT) program for all analytes tested in the laboratory.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and post analytical phases of testing. Findings: The Laboratory Director failed to ensure the laboratory retained documentation of

	validations of the Abbott i-Stat instrument. (See D5421) The Laboratory Director failed to ensure the laboratory performed and retained documentation of the calibration on the Abbott i-Stat instrument at least once every 6 months. (See D5439) The Laboratory Director failed to ensure the laboratory performed two levels of quality controls at least daily on days when patient specimens were tested on the Abbott I-stat instrument. (See D5447) The Laboratory Director failed to ensure the laboratory's test reports provided all the required information for laboratory test reports. (See D5805)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing (PT) program for all chemistry analytes tested in the laboratory in 2020. Findings: Review of the of American Proficiency Institute PT records showed there was not any documentation of proficiency testing performed on the analytes run on the Abbott i-Stat instrument for the Chem 8+ cartridges in 2020. The Chem 8+ i-Stat cartridges that included the following chemistry analytes: sodium, potassium, chloride, calcium, blood urea-nitrogen, total carbon dioxide, creatinine, hematocrit, anion gap, and hemoglobin. During an interview on 12/17/20 at 11:19 AM, Testing Personnel A stated they were not enrolled in proficiency testing for the Chem 8+ analytes in 2020. On 12/17/20 at 2: 25 PM, Testing Personnel A stated the laboratory performed Chem 8+ tests on 76 patients from 1/1/20 to 12/17/20.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Consultant failed to assess the competency of Testing Personnel listed on the Laboratory's Personnel Report for 1 out of 1 personnel (A) from 12/17/18 to 12/17/20. Findings: Review of the CMS-209 form titled, "Laboratory Personnel Report (CLIA)" signed and dated by the Laboratory Director on 12/8/20, showed the Laboratory Director served as the Technical Consultant and listed one testing personnel. Review of the competency assessments for Testing Personnel showed a "New Operators Quiz" was taken by the testing personnel in 2019 and 2020. The "New Operators Quiz" did not contain the following six minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 1. Direct observations of routine patient test

	performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. Direct observations of performance of instrument maintenance and function checks; 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Assessment of problem solving skills. On 12/17/20 at 2:08 PM, the Testing Personnel stated the quiz was the only competency assessment that was performed.