Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2003635	09/25/2018
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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain the documentation on how the laboratory verified the accuracy of the Activated Clotting Time (ACT) test at least twice a year. Findings: The laboratory was enrolled in a proficiency testing (PT) program with American Proficiency Institute (API) to verify the accuracy of the ACT test. Review of the API records showed that the laboratory failed to maintain the PT documentation including the test results records, the "Attestation Statement", and the "Proficiency Testing Performance Evaluation" for the 1st, 2nd, and 3rd events in 2017 and the 1st event in 2018. During an interview on 9/25 /18 at 2:45 PM, Office Manager acknowledged that she was unable to find the PT documentation.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment process failed to identify that the laboratory did not have a written procedure that described how the laboratory verified the accuracy of the Activated Clotting Time (ACT) test at

	least twice a year. Findings: Review of the laboratory's procedure manual showed that the laboratory did not have a procedure that described how the laboratory verified the accuracy of the ACT test at least twice a year. During an interview on 9/25/18 at 3:26 PM, Testing Personnel A acknowledged she did not think they had a procedure on how the laboratory verified the accuracy of the ACT test.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document that the Laboratory Director approved, signed and dated the procedure manual. Findings: The laboratory implemented new procedures in 2017 when they started using the Abbott i-Stat for the Activated Clotting Time test. Review of the procedure manual showed that the laboratory director failed to document that he approved, signed and dated the procedure manual after the laboratory started using the Abbott i-Stat. During an interview on 9/25/18 at 3:40 PM, Testing Personnel A stated that she could not find anything that showed that the Laboratory Director's approved, signed, and dated the procedure manual after the laboratory started using the Abbott i-Stat.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment (QA) plan failed to monitor, access and correct problems identified to ensure the accuracy of patient reports. Findings include: Review of the laboratory's QA logs showed that the laboratory performed a monthly QA checklist from September 2016 to December 2016, but failed to perform the monthly QA checklist after December of 2016. Included in the laboratory's procedure manual was a copy of the monthly QA checklist. Review of the laboratory's QA logs showed that the laboratory failed to perform a monthly patient chart review after December 2016. The policy titled "Quality Assurance Policy" stated that "Once a month, one of the trained staff members will be responsible for pulling 5-10 random patient charts which had Activated Clotting Test performed, and compare the charted results with the logged results". During an interview on 9/25/18 at 3:23 PM, Testing Personnel A stated they did not do the monthly QA checklist or the monthly random patient chart review.