Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0981537	09/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Heart Clinic	100 Pilot Medical Drive Suite 300, Birmingham, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on an observation of reagent cartridges, a review of the policy and procedure manual, including temperature records/logs, and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the laboratory failed to monitor the room temperature of the storage area of the ACT (Activated Clotting Time) cartridges, tested on the Abbott I-stat. The cartridges were required to be at room temperature, prior to testing; and may only be held at room temperature for a limited time, after removing them from the refrigerator. The findings include: 1. Upon the initial tour of the laboratory with the Laboratory Director, the surveyor observed a partial box of ACT cartridges in the drawer of the testing area. "Use by" dates were observed handwritten on the cartridge packages. At this time, the Laboratory Director, stated once the cartridges are removed from the refrigerator, the "use by" dates must be noted on the cartridges, as the shelf life is lessened when not refrigerated. 2. The policy and procedure manual revealed the cartridge shelf life (ACT)/processing temperature: The cartridges, kept at 2 -8 degrees Celsius, should be brought to room temperature (let stand for 5 minutes at room temperature). 3. In an interview at 10:55 AM, the Laboratory Director confirmed the room temperature had not been monitored and documented.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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. This STANDARD is not met as evidenced by: Based on the laboratory's test menu, a review of quality control policies and records, an electronic version of an IQCP (Individualized Quality Control Plan), a lack of documented policies and procedures for Quality Assessment, and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the laboratory failed to establish a complete IQCP, which included the three required parts: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. This affected one of one test, performed by the laboratory. The findings include: 1. During the initial tour of the laboratory, the Laboratory Director identified the only test performed by the laboratory staff as the ACT, which was run on the Abbott I-Stat. 2. A review of the policy and procedure manual revealed a log with ACT cartridge lot numbers/expiration dates, external quality control (levels #1 and #2) lot numbers and expiration dates, and an internal electronic simulator. During an interview at this time, 10:16 AM, the Laboratory Director stated the quality control had been run for several days (16 days) to establish an IQCP. According to the Laboratory Director, the electronic simulator, an internal system check, was run each day of testing, as well as 2 external quality control levels. A section of the policy and procedure manual, labeled QC (Quality Control), signed by the Laboratory Director, revealed the external quality control was tested with every shipment of supplies, which was usually received once per week. The plan was not inclusive of all quality control to be tested, to include the type, number and frequency, as well as, acceptable criteria. 3. At 10:49 AM, a review of the "IQCP" via electronic means, revealed the laboratory did not provide documentation of risk mitigation associated with the five necessary elements, to ensure the risk associated with each element was mitigated across the entire testing process, pre-analytic, analytic and post-analytic processes. The instructions for risk mitigation was to refer to the Abbott manual, which was greater than 500 pages. At this time, the Laboratory Director also failed to show how the data, accumulated as described above, was included or considered with the development of the IQCP. 4. The policy and procedure manual did not include a Quality Assessment program or plan. 5. A review of the quality control records revealed the external controls and internal control (electronic simulator) had been tested for several days between 6/04 and 6/28/18, 7/09; 8/01 and 9/02. This record did not reflect once per week quality control testing of the external quality controls.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the laboratory's test menu, a review of quality control policies and records, an electronic version of an IQCP (Individualized Quality Control Plan), and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the Laboratory Director failed to ensure an IQCP was established to include the three required parts: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. This affected one test, ACT (Activated Clotting Time) of one test, performed by the laboratory. The findings include: 1. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the laboratory's test menu, a review of quality control policies and records, an electronic version of an IQCP (Individualized Quality Control Plan), a lack of documented policies and procedures for Quality Assessment, and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the Laboratory Director failed to ensure an acceptable and complete IQCP was established and implemented, which included the three required parts: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. This affected one test, ACT (Activated Clotting Time) of one test, performed by the laboratory. The findings include: 1. Refer to D5445. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor