Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0981537	12/02/2020
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records and an interview with the Laboratory Director (also the Technical Consultant) and an office manager, the surveyor determined two testing personnel performed proficiency testing on the same specimens (IAC05 and IAC06) for Event #3, 2019 [Activated Clotting Time (ACT)]. This affected one of six proficiency testing events, reviewed by the surveyor. The findings include: 1. A review of the attestation statements for Event #3, 2019 for ACT testing revealed two testing personnel signed for the testing of the same two specimens (IAC05 and IAC06). 2. During an interview on 12/02/2020 at 10:57 AM, the office manager stated sometimes the testing personnel run the same samples to double-check. When the surveyor asked if patients were run in the same manner, the office manager stated patient specimens were not run twice to verify. The Laboratory Director was present for this interview.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing

	samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the laboratory failed to ensure an attestation statement was completed and retained for Event #1, 2020 [Activated Clotting Time (ACT) testing]. This affected one of six proficiency testing events, reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records revealed no attestation statement for Event #1, 2020. 2. During an interview on 12/02/2020 at 11:10 AM, the office manager was asked about the missing attestation statement for Event #1, 2020. The office manager reviewed the proficiency testing records and confirmed the above noted findings.
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 a review of American Proficiency Institute (API) proficiency testing records and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant, the surveyor determined the laboratory failed: a) To implement and document corrective actions to ensure timely submission of proficiency testing results (Event #3, 2018). b) To review and evaluate proficiency testing results from Event #2, 2019. This affected two of six proficiency testing events, reviewed by the surveyor. The findings include: a) A review of the API proficiency testing records revealed the laboratory's worksheet with the recorded results, but no result sheets with grades, returned from API. During an interview on 12/02/2020 at 10:40 AM, the LD stated the specimens were received in the laboratory by non-testing personnel and sat in the refrigerator. The laboratory was not notified of the proficiency testing samples. The LD further stated the specimens were tested, but not within the timeframe to submit to API for grading. The LD stated the laboratory's results were self-evaluated. However, the LD only provided a signed summary of expected results, and no quality assurance documentation or corrective actions to ensure proficiency testing results are timely submitted. b) A review of the proficiency testing records for Event #2, 2019 revealed the LD (also serving as the Technical Consultant) failed to review the results to ensure accuracy (the review/evaluation form was not signed by the LD). During an interview on 12/02/2020 at 10:50 AM, the LD stated she did not do it (sign the form).
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 a review of the 2018-2020 room temperature (RT) records, a review of the policy and procedure manual, a review of the patient test log, and an interview with the office manager and laboratory director, it was determined the laboratory failed to monitor and document the RT each day of patient testing. This affected 7 days in November and December of 2019. The findings includes: 1) A review of the room temperature logs revealed the laboratory failed to monitor and document RT on 4 days in November and on 3 days in December 2019, when patient testing occurred. 2) A review of the policy and procedure manual revealed the test cartridges used with the ISTAT should stand at room temperature (established at 60 -78 degrees Fahrenheit) for five minutes, prior to running the test. The patient test log indicated approximately fourteen patients had been tested, during the time period when the room temperature was not monitored. 3) During an interview with the office manager on 12/2/2020 at 12: 10 PM, the surveyor asked if the staff monitored room temperatures on the days listed above from November and December of 2019. The office manager confirmed the missing documentation. The laboratory director was present during the interview.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records, a lack of documentation, and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant, the surveyor determined the LD failed to ensure the staff returned the proficiency testing results to API by the submission deadline, to ensure grading by the provider for Event #3, 2018 (Activated Clotting Time testing). This affected one of six testing events, reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records revealed the laboratory's worksheet with the recorded results, but no result sheets with grades, returned from API. 2. During an interview on 12/02/2020 at 10:40 AM, the LD stated the specimens were received in the laboratory by non-testing personnel and sat in the refrigerator. The laboratory was not notified of the proficiency testing samples. The LD further stated the specimens were tested, but not within the timeframe to submit to API for grading. The LD stated the laboratory's results were self-evaluated. However, the LD only provided a signed summary of expected results, and no quality assurance or corrective actions to ensure proficiency testing results are timely submitted.
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 a review of the policy and procedure manual, a review of the proficiency testing records, a lack of documentation, and an interview with the Laboratory Director (also serving as the Technical Consultant) and an office manager, the surveyor determined the Laboratory Director (LD) failed to establish a quality assurance program to ensure a) Attestation statements were signed and retained. b) Proficiency Testing results were reviewed and evaluated, and corrective actions were implemented and documented, when necessary. c) Proficiency Testing results were returned to the proficiency testing provider within the submission timeframes, to ensure grading. d) Chart reviews were performed to ensure accuracy of reporting and recording in the medical records. The findings include: a) Refer to D2015. b) Refer to D5221. c) Refer to D6017. d) During an interview on 12/02/2020 at 12:27 PM with the LD and an office manager , the surveyor inquired of the Quality Assurance Policy and Procedure, to include random chart reviews. The office manager stated the laboratory did not perform chart reviews or quality assurance, as explained. The LD stated the Quality Assurance Policy should be on the flash-drive, which was attached to one of the laboratory manuals. The LD took the flash-drive out of the room to review for the policy, returned and stated she would have to mail the policy and procedure back to the laboratory.