

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0981537	(X3) Date Survey Completed 08/08/2024
Name of Provider or Supplier Birmingham Heart Clinic	Street Address, City, State 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Director of Diagnostics (DOD), the Laboratory Director failed to sign the PT attestation statements for the specialties in Hematology and Chemistry. This was noted for three of six events reviewed in 2023. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2023 Hematology 1st Event. b) 2023 Chemistry 1st Event. c) 2023 Chemistry 2nd Event. 2. During an interview on 8/8/24, at 10:22 AM, the DOD confirmed the above findings.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Director of Diagnostics (DOD), the laboratory failed to ensure documentation of PT review pages for specialties in Hematology and Chemistry. This was noted for five of nine events reviewed from 2023 through 2024. The findings include: 1. A review of the API PT records revealed no documentation</p>

of a review from the Laboratory Director, or designee, for the following surveys: a) 2023 Hematology 3rd Event. b) 2023 Chemistry 3rd Event. c) 2024 Hematology 1st Event. d) 2024 Chemistry 1st Event. e) 2024 Chemistry 2nd Event. 2. During an interview on 8/8/2024, at 10:22 AM, the DOD confirmed the above findings.

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 the review of the Abbott iSTAT Chemistry-8 cartridge QC (Quality Control) documentation, the iSTAT Value Assignment Sheet (VAS) documentation, and an interview with the Director of Diagnostics, the laboratory failed to ensure Chem-8 reference intervals were updated with each new lot number. This was noted from the previous survey on 10/4/2022 to current survey of 8/8/24. The findings include: 1. A review of the Chem-8 cartridge QC revealed QC was performed monthly as per the procedure, however the laboratory failed to update reference ranges with every lot change since the previous survey of 10/4/22. There was no evidence of documentation of verification for acceptable QC. 2. A further review of the VAS revealed, "Use Value Assignment Sheets to locate the correct target values and ranges for your i-STAT test cartridge controls." 3. During the exit interview on 8/8/24 at 1:00 PM, the DOD confirmed she was unaware of downloading the VAS and updating the ranges with every new lot.

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 tour, a review of the IQCP (Individualized Quality Control Plan), and an interview with the DOD (Director of Diagnostics), the surveyor determined the laboratory failed to establish an IQCP, which included the three required parts: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. This affected one of two tests performed by the laboratory. The findings include: 1. During the initial tour of the laboratory, the DOD identified two tests performed by the laboratory staff, the ACT and Chem-8 cartridges which are

performed on the Abbott I-Stat. 2. A review of the IQCP revealed the ACT test only. There was no evidence of a documented IQCP for the Chem-8 cartridge. An IQCP must address the potential failures and errors identified in the entire testing process: preanalytic, analytic and postanalytic phases of testing. 3. During an interview on 8/8/24 at 11:55 AM, the DOD confirmed there was no IQCP for the Chem-8 cartridge.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the iSTAT Chemistry-8 QC (Quality Control) log, the Chem-8 patient log, and an interview with the DOD (Director of Diagnostics), the laboratory failed to document QC lot numbers and expiration dates for each lot number prior to use for patient testing. This was noted for 51 days of 16 months reviewed in 2023 through 2024. The findings include: 1. A review of the Chem-8 QC log revealed no documentation of QC from when the last lot expired to when the new lot was put into use for the following: a) Lot# H23005A was put into use 5/4/23 and expired 7/7/23; 51 days later, b) Lot# H23094A was put into use 8/28/23 and expired 10/1/23. 2. A review of the patient log revealed 17 patient Chem-8 tests were performed on the 51 days of no QC documentation. 3. During an interview on 8/8/24 at 12:31 PM, the DOD confirmed QC documentation was missed.

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 tour, a review of the IQCP (Individualized Quality Control Plan), and an interview with the DOD (Director of Diagnostics), the surveyor determined the laboratory failed to establish an IQCP, which included the three required parts: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. This affected one of two tests performed by the laboratory. The findings include: 1. Refer to D5445. .