| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0259599 | 05/06/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Atlanta Diabetes Associates | 1800 Howell Mill Road, Suite 450, Atlanta, GA | |

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 |
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| **D0000** | On June 01, 2022 an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA documents review revealed the lack of a QA checklist and documentation from 2020 to 2022. 2. No evidence of a problem log for failed QC for CBC (Beckman Coulter DxH 520), Chemistry (AIA 2000 ST TOSOH) Analyzers or any other problems arising in the lab during testing. 3. An interview with the Laboratory coordinator (TP#2 CMS209) on 05/06/2022 at 12:15 PM in the conference room confirmed the lack of adequate QA checklist and problem logs for the analyzers 2020 to 2022. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials |

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| | using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on Hematology maintenance, Quality Control (QC) documents review and staff interview, it was determined that the laboratory did not have a policy in place to monitor Quality Control (QC) on the Beckman Coulter DxH 520 Hematology analyzer and AIA 2000 ST TOSOH Chemistry Analyzers in 2020 to 2022. Findings include: 1. Hematology/ Chemistry QC review revealed there were NO Levey Jennings graphs or EQC data to monitor Quality Control runs in 2020 to 2022. 2. Laboratory coordinator's (TP#2 CMS 209) interview on 05/06/2022 at approximately 12:40 PM in the review room confirmed the laboratory did not have Levey Jennings graphs nor EQC to monitor hematology/ Chemistry controls in 2020 to 2022. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Control(QC) documents review and staff interview, the Lab Director (LD) failed to ensure that proper QA guidelines are followed including regular review of instrument Quality Control (QC) data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Quality Control (QC) documents review revealed the laboratory director did not review daily (QC) instrument data and implement a QC monitor program identify and correct problems for Hematology and Chemistry as required in 2020 to 2022. 2. An interview with the lab supervisor (TP#2 CMS209) in the review room on 05/06/2022, at approximately 12:50 PM, confirmed the LD did not review the aformentioned (QC) data and monitor for 2020 to 2022. |