Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0259599	**(X3) Date Survey Completed** 03/20/2024
Name of Provider or Supplier Atlanta Diabetes Associates	**Street Address, City, State** 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
D0000	A proficiency testing desk review was completed on March 20, 2024. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of the American Proficiency Institute (API) reports, the laboratory

	failed to successfully participate in proficiency testing (PT) for Blood Urea Nitrogen (BUN), Total Protein (TP), & Chloride (CL) resulting in the non-initial unsuccessful participation for BUN, TP, & CL. Refer to D 2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of the CMS CASPER 155 report and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to demonstrate satisfactory performance in three of four testing events for Blood Urea Nitrogen (BUN) and Total Protein (TP) and four of seven testing events for Chloride (CL). Findings: 1. A review of Report 155 revealed the laboratory failed to score at least 80% for the analytes BUN, CL, and TP during the following events: BUN 2023 Event 1 Score 60% 2023 Event 3 Score 0% 2024 Event 1 Score 0% TP 2022 Event 3 Score 0% 2023 Event 1 Score 40% 2023 Event 3 Score 0% CL 2022 Event 1 Score 40% 2022 Event 3 Score 0% 2023 Event 3 Score 0% 2024 Event 1 Score 20% 2. A review of the API reports revealed and confirmed the failed PT scores for the analytes BUN, CL, and TP.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of the API reports, the laboratory director failed to provide overall management and direction for successful participation in PT. The laboratory director failed to ensure PT samples were tested as required. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on review of the CMS CASPER Report 155 and the API 2022, 2023, & 2024 PT evaluation reports, the laboratory director failed to ensure successful PT participation. Refer to D 2096