

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0259599	(X3) Date Survey Completed 01/11/2023
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 January 11, 2023. 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 conditions were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by:</p>

	<p>The laboratory failed to maintain satisfactory proficiency testing (PT) performance for Chloride (CL) in 2022 events one and three resulting in the first unsuccessful occurrence for CL. Refer to D 2130</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two of three events (1st and 3rd events of 2022) resulting in the first unsuccessful performance for chloride (CL). Findings : 1. Review of Casper Reports 153 and 155 disclosed the laboratory failed CL : - 2022 event 1 with a score of 40% - 2022 event 3 with a score of 0%. 2. Review of the laboratory's proficiency testing reports from American Proficiency Institute (API) confirmed the laboratory failed chloride on Events 1 and 3 of 2022 resulting in the first unsuccessful performance.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: The laboratory director failed to maintain compliance with successful Chloride (CL) proficiency testing (PT) for two of three events, resulting in the first unsuccessful performance for CL. Refer to D6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three events (1st and 3rd events of 2022), resulting in the first unsuccessful occurrence chloride (CL). Findings: 1. Review of Casper</p>

Reports 153 and 155 disclosed the laboratory failed CL: - 2022 event 1 with a score of 40% - 2022 event 3 with a score of 0% 2. Review of the laboratory's proficiency testing reports from American Proficiency Institute (API) confirmed the laboratory failed CL on 2022 Events 1 and 3, resulting in the first unsuccessful performance.