

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0257514	(X3) Date Survey Completed 01/11/2023
Name of Provider or Supplier Children's Clinic, The	Street Address, City, State 1550 Doctors Drive, Lagrange, 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 D6000
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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance 3 of 5 testing events for automated white blood cell (WBC) differential analyte in 2021 event 2, 2022 events 2 and 3, resulting in the 1st unsuccessful occurrence for WBC differential. Refer to D2130</p>

<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) Casper Reports 153 and 155 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three of five testing events (2nd event of 2021, 2nd and 3rd events of 2022), resulting in the 1st unsuccessful occurrence for automated white blood cell differential (WBC Diff). Findings include: 1. A review of Casper Reports 153 and 155 disclosed the laboratory failed WBC Diff on the following: 2021 Event 2 WBC Diff Score 60% 2022 Event 2 WBC Diff Score 0% 2022 Event 3 WBC Diff Score 20% 4. A review of the laboratory's proficiency testing reports from American Proficiency Institute (API) confirmed the laboratory failed WBC Diff with the aforementioned scores.</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 white blood cell differential (WBCD) proficiency testing (PT) for three of five events, resulting in the 1st unsuccessful performance for WBCD. 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 review of the Centers for Medicare and Medicaid Casper Reports 153 and 155 and the laboratory's proficiency testing (PT) evaluation reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance for three of five proficiency testing events for the automated white blood cell differential (WBCD) resulting in the 1st unsuccessful PT occurrence for WBCD. Refer to D2130</p>