

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0909399	(X3) Date Survey Completed 02/03/2021
Name of Provider or Supplier Dawson Pediatrics Pc	Street Address, City, State 300 Dawson Commons Circle Suite 320, Dawsonville, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 3, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assurance (QA) document review and an interview with the lab manager, the laboratory director failed to document all general laboratory systems QA activities as required. Findings include: 1. QA documents review revealed there were monthly QA documentation available but they were not reviewed and signed by the laboratory director who also acts as the Technical Consultant (TC) on a consistent basis in 2019 and 2020. 2. Room temperature logs, Humidity logs and refrigerator logs were not reviewed and signed by the laboratory director on a consistent basis in 2019 and 2020. 3. An interview with the laboratory manager in the break room on 02/03/2021 at approximately 12:30 p.m. confirmed lack of consistent QA oversight by the laboratory director for the aforementioned period.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on Personnel competency records review and an interview with the laboratory manager, the lab director who is also the technical consultant (TC) failed to perform annual competencies on all Testing Personnel (TP) in 2019 and 2020 as required. Findings include: 1. 2019 and 2020 competency records review revealed the TC did not perform annual competencies on (TP #s 1 - 4 CMS 209). The competencies were instead performed by the laboratory manager who is a Certified Medical Assistant (CMA) 2. An interview with laboratory manager on 02/03/2021 in the break room at approximately 12:40 p.m. confirmed annual competencies for the aforementioned testing personnel (TP) were not performed by the Technical Consultant(TC/ LD).