

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0997580	(X3) Date Survey Completed 06/21/2024
Name of Provider or Supplier Georgetown Pediatrics	Street Address, City, State 416 Pirkle Ferry Road Suite 300 J, Cumming, 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 June 21, 2024. 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 Assessment (QA) document review and staff interview, the laboratory failed to document ALL quality assessment activities on a monthly basis as stated in their QA policy manual from 2022 to 2024. Findings: 1. A review of the laboratory QA documents revealed the Technical Consultant (TC), who is also the Lab Director, did not review and sign ALL monthly Quality Assessment(QA) activities including; daily temperatures, daily maintenance and QC reviews, incubator, humidity, refrigerator and weekly eyewash equipment checks from 2022 thru the date of survey June 21, 2024. 2. Interviews with the nurse manager on 06/21/2024, at approximately 12:10 pm in the review room confirmed NO (QA) checklist activities were monitored and signed off by the Lab Director from 2022 thru day of survey June 21, 2024.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on documents review and interview with the nurse manager, the Lab Director (LD) failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory from 2022 to 2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Quality Assurance (QA) document review revealed the Lab Director, who is also the Technical Consultant (TC), did NOT realize that monthly Quality Assessment (QA) activities were not performed from 2022 to 2024.. 2. An interview with the nurse manager in the review room on 06/21/2024 at approximately 12:35 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory's testing and (QA) activities from 2022 to 2024.