

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D0978199</p>	<p>(X3) Date Survey Completed</p> <p>11/13/2024</p>
<p>Name of Provider or Supplier</p> <p>Middle Georgia Pediatrics Llc</p>	<p>Street Address, City, State</p> <p>1508 B Hardeman Avenue, Attn Michelle Kelly, Macon, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>A recertification survey was performed on November 13, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVEL: D6000 - Laboratory Director Responsibilities - 493.1407(d)</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: Based on the review of the Quality Control (QC) for the Sysmex XN-330, Hematology Analyzer (Sysmex), the Laboratory Director failed to provide overall management and direction. The LD failed to document review of the QC documents for the Sysmex from 1/10/2023 thru the date of survey, 11/13/2024. This a CONDITION level citation. REFERENCE: D6020 .Laboratory Director Responsibilities 493.147 (e) (5)</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:

Based on the review of the Quality Control (QC) for the Sysmex XN-330, Hematology Analyzer (Sysmex) and staff interview, the Laboratory Director (LD) failed to provide overall management and direction. The LD failed to document review of the QC documents for the Sysmex from 1/10/2023 thru the date of the survey date, 11/13/2024. Findings: 1. Review of the Sysmex QC documents from January 2023 thru November 2024, the LD failed to document review of the QC documents 2. Staff interview with the Office Manager and Lab supervisor, on 11/13/2024, at approximately 3pm, in the breakroom, confirmed the statement above.