

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0263537	<b>(X3) Date Survey Completed</b>  12/02/2025
<b>Name of Provider or Supplier</b>  Internal Medicine Associates Of Middle Georgia Pc	<b>Street Address, City, State</b>  97 Martin Luther King Jr Dr, Forsyth, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on DECEMBER 2, 2025. 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:
<b>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: A review of 2023 - 2025 API Proficiency Testing Records confirmed that corrective actions were not documented for the proficiency scores less than 100% as required. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 API Proficiency Testing Records confirmed the following: a. 2024 Hematology Event 1, LYMPH% score of 80%; b. 2024 Hematology Event 3, PLT score of 80%; and c. 2025 Hematology Event 1, no results submitted for evaluation. 2. A review of the aforementioned records confirmed that the required corrective action documentation was not performed. 3. An exit interview, with Testing Personnel, on December 2, 2025, at 2:00pm confirmed that corrective actions were not performed or documented for the proficiency scores less than 100%.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

A review the current Procedure Manual confirmed that the laboratory failed to have a written procedure manual for all tests, assays, and examinations performed by the laboratory. THE FINDINGS INCLUDE: 1. An interview with the laboratory staff confirmed that a Procedure Manual, containing written procedures for all laboratory processes, was not available. 2. An exit interview, with Testing Personnel, on December 2, 2025, at 2:00pm confirmed that the laboratory failed to have a written procedure manual for all tests, assays, and examinations performed by the laboratory.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Personnel Records, 2023 - 2025 API Proficiency Testing Records, 2023 - 2025 Quality Control Records, and 2023 - 2025 Temperature Records confirmed that the Laboratory Director failed to provide oversight of overall operations and administration of the laboratory facility. THE FINDINGS INCLUDE: Reference: D2128, D5401, D6020, and D6028

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Personnel Records, 2023 - 2025 API Proficiency Testing Records, 2023 - 2025 Quality Control Records, and 2023 - 2025 Temperature Records confirmed that the Laboratory Director failed to ensure that the quality assessment programs were established and maintained. THE FINDINGS INCLUDE: 1. A review of the aforementioned records confirmed that the Laboratory Director's quality assurance records review documentation was not performed. 2. A review of the aforementioned records confirmed that quality

assurance was performed by Testing Personnel #5 ( See CMS Form 209 Laboratory Personnel Report) without a letter of delegation from the Laboratory Director. 3. An exit interview, with Testing Personnel, on December 2, 2025, at 2:00pm confirmed that the Laboratory Director failed to perform the quality assessment reviews or provide a letter of delegation for laboratory personnel to perform the task.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(10)

(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:  
A review of 2023 - 2025 Personnel Records confirmed that the Laboratory Director failed to ensure the training and ongoing competency review of of the laboratory personnel was performed by qualified personnel. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel records revealed that unqualified Testing Personnel performed competencies on each other. 2. A review of laboratory records confirmed that letters of delegation, transferring competency assessments from the Laboratory Director, was not available on the date of survey. 3. An exit interview, with Testing Personnel, on December 2, 2025, at 2:00pm confirmed that the Laboratory Director failed to ensure the training and ongoing competency of the laboratory personnel by qualified personnel.