

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0263537	<b>(X3) Date Survey Completed</b>  01/14/2022
<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 January 14, 2022. 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>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathology (CAP) Proficiency Testing (PT) provider documents for the years 2020 and 2021 and staff interview, the Laboratory failed to verify the accuracy of the specialty of Hematology. Findings: 1. Review of the CAP PT documents for 2020 and 2021, for the specialty of Hematology, the facility received notes on the Evaluation that the submitted results were not graded due to "not enough participants to evaluate". Further investigation revealed that the Sample Kit was not correct for the testing of the Abbott Emerald, instead was listed as the Beckman/ Coulter AcT diff Hematology Analyzer. 2. Interview with staff #2 (CMS form 209)and the Laboratory Director, on January 14, 2022, at approximately 11:30 am, in the office confirmed the aforementioned statement.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) provider and staff interview, the Laboratory Director (LD) failed to identify the the appropriate instrument was documented on the CAP Evaluation Report for the year 2021 and 2022 for the Specialty Hematology. Findings: 1. Review of the CAP PT evaluation reports for the specialty of Hematology, revealed that the instrument that was listed on the result form was the Beckman/Coulter, AcT diff Hematology Analyzer. The Abbott Cell-Dyn Emerald was the current testing instrument for Specialty of Hematology for the last four years. 2. Interview with staff #2 (CMS 209 form) and the LD, on January 14, 2021 at approximately 11:30 am, in the office, confirmed the aforementioned statement.