Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0263537	**(X3) Date Survey Completed** 01/05/2023
Name of Provider or Supplier Internal Medicine Associates Of Middle Georgia Pc	**Street Address, City, State** 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.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	A proficiency testing desk review was completed on January 05, 2023. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition level deficiencies were cited: D2016 - 42 C.F.R. 493.803 Successful participation [proficiency testing] D6000 - 493.1403 Laboratory Director, Moderate Complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of College of American Pathologist (CAP) reports, the laboratory

	failed to maintain satisfactory proficiency testing (PT) performance for automated hemoglobin (HGB) in 2022 events 1, 2, and 3; hematocrit (HCT) and white blood cell count (WBC) in 2022 events 1, 2, 3, and 2023 event 1, resulting in the non-initial unsuccessful participation for HCT, HGB, and WBC. Refer to D 2130
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER Report 155 and review of the College of American Pathologist (CAP) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three testing events (1st, 2nd, and 3rd events of 2022) resulting in the non-initial unsuccessful participation for automated hemoglobin (HGB). Four testing events (1st, 2nd, and 3rd events of 2022 and 1st event of 2023), resulting in the non-initial unsuccessful participation for automated hematocrit (HCT) and white blood cell count (WBC). Findings include: 1. A review of CASPER Report 155 revealed the laboratory failed HCT on the following: 2022 Event 1 HCT Score 60% 2022 Event 2 HCT Score 0% 2022 Event 3 HCT Score 40% 2023 Event 1 HCT Score 0% 2. A review of CASPER Report155 revealed the laboratory failed WBC on the following: 2022 Event 1 WBC Score 0% 2022 Event 2 WBC Score 40% 2022 Event 3 WBC Score 20% 2023 Event 1 WBC Score 20% 3. A review of CASPER Report155 revealed the laboratory failed HGB on the following: 2022 Event 1 HGB Score 20% 2022 Event 2 HGB Score 20% 2022 Event 3 HGB Score 0% 4. A review of the laboratory's proficiency testing reports from CAP confirmed the laboratory failed HCT, HGB, and WBC with the aforementioned scores.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of College of American Pathologist (CAP) reports, the laboratory director failed to provide overall management and direction for PT performance. The laboratory director failed to ensure PT samples were tested as required. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based review of the Centers for Medicare and Medicaid (CMS) CASPER Report 155 and the laboratory's College of American Pathologist (CAP) proficiency testing (PT) evaluation reports, the laboratory director failed to provide overall management and direction for PT performance. The laboratory director failed to ensure PT samples were tested as required. Findings include: 1. A review of CASPER Report 155 revealed the laboratory failed HCT on the following: 2022 Event 1 HCT Score 60% 2022 Event 2 HCT Score 0% 2022 Event 3 HCT Score 40% 2023 Event 1 HCT Score 0% 2. A review of CASPER Report155 revealed the laboratory failed WBC on the following: 2022 Event 1 WBC Score 0% 2022 Event 2 WBC Score 40% 2022 Event 3 WBC Score 20% 2023 Event 1 WBC Score 0% 3. A review of CASPER Report155 revealed the laboratory failed HGB on the following: 2022 Event 1 HGB Score 20% 2022 Event 2 HGB Score 20% 2022 Event 3 HGB Score 0% 4. A review of the laboratory's proficiency testing reports from CAP confirmed the laboratory failed HGB, HCT, and WBC with the aforementioned scores.