Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0120827	06/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Associates, Pa	201 Laurel Heights Drive, Bridgeton, NJ	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained from the American Association of Bioanalysts (AAB) for Chemistry and Nonchemistry events from May 2019 to the date of survey. The findings include: 1. The laboratory did not evaluate Code # (This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guild to your performance. However, exercise caution in evaluating your results) response from AAB for the following: a) Triiodothyronine Total (TT3) in Chemistry events Q2 and Q3 2019, and 2020, and Q1 2021. b) Leukocyte, Hemoglobin, Hematocrit, Platelets, Neutrophil, and Lymphocyte % in Nonchemistry event Q3 2020. 2. The LD confirmed on 6/24/21 at 10:00 am that the laboratory failed to evaluate the above mentioned coded results.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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).

	This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of Endocrinology and Hematology tests performed the American Association of Bioanalysts (AAB) form May 2019 to the date of survey. The findings include: 1. The laboratory did not evaluate Code # (This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guild to your performance. However, exercise caution in evaluating your results). The analyte's below received Code #: a) Triiodothyronine Total (TT3) in Chemistry events Q2 and Q3 2019, and 2020, and Q1 2021 but received a score of 100 %. b) Leukocyte (LEU), Hemoglobin (Hgb), Hematocrit, Platelets, Neutrophil, and Lymphocyte % in Nonchemistry event Q3 2020 but received a score of 100%. 2. Upon evaluation analytes scored as below: 2a. Event Q2 Chemistry 2019 the laboratory scored 0% for TT3 a) Challenge 1 result 2.73 Grading Range (GR) 0-2.09. b) Challenge 2 result 4.71 GR .06-3.29. c) Challenge 3 result 5.35 GR 0-3.94. d) Challenge 4 result 5.59 GR 0-4.11. e) Challenge 5 result 3.9 GR .04-3.02. 2b. Event Q3 Chemistry 2019 the laboratory scored 20% for TT3. a) Challenge 11 result 6.06 GR 0-4.08. b) Challenge 13 result 3.27 GR 0-2.7. c) Challenge 14 result 5.8 GR 0-3.81. d) Challenge 15 result 6.97 GR 0-4.6. 2c. Event Q2 Chemistry 2020 the laboratory scored 20% for TT3. a) Challenge 6 result 5.75 GR 0-4.44. b) Challenge 7 result 5.27 GR 0-3.89. c) Challenge 8 result 5.74 GR 0-4.13. d) Challenge 10 result 4.27 GR 0-3.39. 2d. Event Q3 Chemistry 2020 the laboratory scored 0% for TT3. a) Challenge 11 result 5.97 GR 0-4.56. b) Challenge 12 result 4.23 GR 0-3.94. c) Challenge 13 result 3.87 GR 0-3.57. d) Challenge 14 result 6.13 GR 0-4.57 e) Challenge 15 result 4.27 GR 0-4.1. 2e. Event Q3 Nonchemistry 2020 the laboratory scored 40% for LUE. a) Challenge 11 result 6.1 GR 6.3-8.6. b) Challenge 13 result 2.1 GR 2.6-3.5. c) Challenge 15 result 2.2 GR 2.7-3.6. 2f. Event Q3 Nonchemistry 2020 the laboratory scored 40% for Hgb. a) Challenge 11 result 12.2 GR 13.1-15. b) Challenge 13 result 4.9 GR 5.6-6.5. c) Challenge 15 result 4.8 GR 5.7-6.5. 2g. Event Q3 Nonchemistry 2020 the laboratory scored 0% for Lymph%. a) Challenge 11 result 12.6 GR 16-31.3. b) Challenge 12 result 11.1 GR 12.3-20.1. c) Challenge 13 result 17.6 GR 28.7-44.2. d) Challenge 14 result 10.7 GR 12.2-19.9. e) Challenge 15 result 17.6 GR 29.9-43.7. 3. All analytes above revied a score of 100% from AAB 4. There was no documented evidence corrective action or off cycle PT was performed. 5. The TP confirmed on 6/24/21 at 10:45 am the laboratory did not verify the accuracy of all analytes performed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate results when they received an unacceptable score in Chemistry tests performed with the American Association of Bioanalysts (AAB) for the third event in the calendar year 2019. The findings include: 1. The laboratory received an unacceptable score for Thyroid Stimulating Hormone sample 13. 2. There was no documented evidence that the laboratory investigated the failure. 3. The TP confirmed on 6/24/21 at 10:10 am that the laboratory did not review and document an evaluation of unacceptable PT results.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Performance Specification records and interview with the Testing Personnel (TP), the laboratory failed to verify Normal Reference Range (NRR) for Complete Blood Count (CBC) performed on the CELL-DYN Emerald analyzer from July 2020 to the date of survey. The TP confirmed on 6/24/21 at 12:00 pm that the laboratory did not perform NRR verification.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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 surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Endocrinology and Hematology tests performed with the American Association of Bioanalysts (AAB) for events Q2 and Q3 2019, 2020, and Q1 2021. The TP confirmed on 6/24/21 at 11:30 pm that the AAB PT results were not reviewed.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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: Based on surveyor review of the laboratory Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was accurately established to assure quality of laboratory services for Hematology tests provided from 11/20/18 to the date of the

	survey. The finding includes: 1. The QA procedure did not include a review to ensure that patient Work Records (WR) were accurately scanned into the patients Electronic Medical Record (EMR). 2. The TP confirmed on 6/24/21 at 11:45 am that a QA program was not accurately established.