Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641797	06/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Associates	121 North 20th Street #6, Opelika, AL	

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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on a review of AAB (American Association of Bioanalysts) proficiency testing records, a review of CMS (Centers for Medicare and Medicaid Services) CASPER reports, and an interview with the Technical Consultant [also Testing Personnel (TP) #1], the surveyor determined the laboratory failed to ensure proficiency testing results were released and reported to HHS (Health and Human Services) to assure CLIA (Clinical Laboratory Improvement Amendments) was able to determine the laboratory's performance with proficiency testing. This affected the survey review period from September 13, 2018 - June 15, 2021. The findings include: 1. The pre-survey offsite review of the CMS CASPER reports revealed no proficiency testing scores for the laboratory were reported to HHS for the review period from September 2018 - June 15, 2021. 2. An on-site review of the AAB proficiency testing records revealed the CLIA number was not listed on the reports sent to the laboratory from AAB, which indicates the proficiency testing provider had not been provided the necessary information to release the laboratory's results to HHS. 3. During an interview on June 15, 2021 at 12:33 PM, the surveyor inquired of the Technical Consultant if AAB had been contacted to release the proficiency testing scores to the national data base for compliance determination. The Technical Consultant stated the proficiency testing was ordered through the McKesson representative, who she assumed had taken care of all the reporting requirements. After reviewing the proficiency testing reports and forms for the CLIA number (not listed), the Technical Consultant confirmed the above noted findings.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of AAB (American Association of Bioanalysts) proficiency testing records and an interview with the Technical Consultant (TC), the surveyor determined the laboratory failed to verify the accuracy of "direct bilirubin" testing, at least twice annually. The laboratory routinely participated in organized proficiency testing for Chemistry, specifically "direct bilirubin" testing, which was not offered by the proficiency testing provider used, according to the TC. This affected seven testing events, reviewed by the surveyor. The finding include: 1. A review of the AAB proficiency testing records for 2018 (Event #3) - 2021 (Event #1) revealed the laboratory resulted the "direct bilirubin" for each event, with the following scores: a) Event #3, 2018; Eighty percent (80 %), performed on the Architect (discontinued at the end of 2018). b) Event #1, 2019; 40 % (Chemistry testing now performed on a Vitros 5600) c) Event #3, 2019; 40 % d) Event #1, 2020; 60 % e) Event #2, 2020; 60 % f) Event #3, 2020; 20 % g) Event #1, 2020; 40 % The laboratory did not document corrective actions for these failing scores and scores less than one hundred percent accuracy. The laboratory also failed to evaluate these scores to determine accuracy of testing. 2. During an interview on June 15, 2021 at 12:00 PM, the TC stated the laboratory provided testing of that fraction of bilirubin, which AAB did not provide proficiency testing. The TC stated after Event #1 2020, she spoke to AAB, who told her the laboratory's method of test performance was not offered by AAB (this was not documented). When the surveyor asked if another provider for bilirubin testing had been sought for proficiency testing, the TC stated no, and confirmed no other accuracy verifications had been done and no corrective actions were documented. The TC also stated, when this was realized, the laboratory stopped charging for this testing, but continued to result the test on the patients' reports. When the surveyor asked if a diagnosis and/or treatment could possibly follow the result, the TC stated, "Possibly."
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 a review of AAB (American Association of Bioanalysts) proficiency testing records and an interview with the Technical Consultant (TC), the surveyor determined the laboratory failed to implement and document corrective actions for proficiency testing scores of less than one hundred percent and failing scores. This affected eight of eight proficiency testing events, reviewed by the surveyor. This is a repeat deficiency. The findings include: 1. A review of AAB proficiency testing records revealed the following: a) Hematology Event #3, 2018, wrong testing module reported. The TC performed a self-evaluation. However, the TC incorrectly graded the results for the WBC (White Blood Cell) Differential as 100 % (one hundred percent) and documented no corrective actions for this score of less than one hundred percent. In an interview on June 15, 2021, at 12:00 PM, the TC confirmed the wrong testing

	module was used, when the results were sent to AAB, and the laboratory performed a self evaluation, which was incorrectly graded. The TC confirmed no corrective actions were done. Chemistry Event #3, 2018; the laboratory scored 60 % for the TSH (Thyroid Stimulating Hormone) and 80 % for the direct bilirubin. At 12:32 PM, the TC reviewed the results and confirmed the laboratory did not document corrective actions. b) Hematology Event #1, 2019, wrong testing module reported. The TC performed a self-evaluation, which yielded several analytes with less than 100 % to failing scores. No corrective actions were implemented. At 12:32 PM, the TC stated the specimens were rerun in October of 2019, at least six months following the grading period. Chemistry Event #1, 2019, ALT (Alanine Aminotransferase) = 80 % (The laboratory reran the specimen, which resulted in the same result). The direct bilirubin (dbili) score was 40 % (the laboratory documented the specimens were rerun; however the results were still questionable). c) Chemistry Event #2, 2019: The laboratory received zero percent scores for the TSH and the FT4 (Free Thyroxine), because they did not report the results to AAB. On June 15, 2021 at 1:44 PM, the TC stated the laboratory failed to send the results to AAB, due to an oversight, and thus had to perform a self-evaluation. Although the laboratory scored 100 % via self-evaluation, the laboratory did not address the process of submission, and implement and document corrective actions to ensure this does not recur. d) Hematology Event #3, 2019; WBC score = 80 %, WBC Differential = 86 %. The laboratory reran the specimens, but obtained the same scores of less than one hundred percent. No other corrective actions were documented. Chemistry Event #3, 2019: HDL (High-density lipoprotein) = 80 %; dbili = 40 %; PSA (Protate Specific Antigen) = 0 %; vitamin B12 = 0 %; and vitamin D = 0 %. At 1:54 PM, the technical consultant stated the laboratory did not document corrective actions for Event #3, 2019. e) Chemistry Event #1, 2020; dbili = 60 % (corrective actions were not implemented nor documented) f) Hematology Event #2, 2020; WBC Differential = 80% (The laboratory documented corrective actions as "needs new instrument.") Chemistry, Event #2, 2020; dbili = 60 % (corrective actions were not implemented nor documented) g) Chemistry, Event #3, 2020; dbili = 20 % (corrective actions were not implemented nor documented) h) Chemistry, Event #1, 2021; dbili = 40 % (no corrective actions were documented)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of installation and validation records for the Cell-Dyn Emerald and the Vitros 5600, and an interview with the Technical Consultant (TC), who is also Testing Personnel #1, the surveyor determined the Laboratory Director (LD) failed to review and approve the installation and validation of the manufacturers' performance specifications of the two instruments, prior to the laboratory staff analyzing patient specimens and reporting the results. This affected two of two new instruments installed in the laboratory, since the previous survey on September 13, 2018. The

	findings include: 1. During the tour of the laboratory on June 15, 2021 at 9:45 AM, the TC stated the laboratory had installed two new instruments: the Hematology analyzer, Cell-Dyn Emerald, and the Chemistry analyzer, Vitros 5600. 2. A review of the installation and validation binder for the Emerald revealed the instrument was installed in December of 2020; and the start-up and carryover, precision, calibration, accuracy and reportable range study were performed on 12/15/2020. The LD's signature was not found on any of these studies, nor on a summary page. The surveyor noted the TC had signed the reportable range study, and dated, 12/22/2020. 3. At 2:06 - 2:09 PM on June 15, 2021, the TC confirmed she signed the reportable range study, as she entered the raw data, accumulated by the manufacturer's representative, for analyses and graphs. The surveyor inquired if the LD had reviewed and signed his approval of the validation studies and use of the instrument in the laboratory. The TC stated she did not believe the LD ever reviewed the validation, and she was not aware of the requirement. The TC stated patient testing began the same day the studies were done, 12/15/2020. 4. A review of installation and validation binder for the Vitros 5600 revealed the instrument was installed in December of 2018; and the precision, accuracy, method comparison and reportable range study were performed on 12/20 /2018. The LD's signature was not found on any of these studies, nor on a summary page. 5. At 4:04 PM on June 15, 2021, the TC stated the LD had not reviewed nor signed the validation studies for the Vitros 5600, and she was not aware this was a requirement.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of quality assurance meeting notes, a review of proficiency testing records, and interviews with the Technical Consultant (also testing personnel #1), the surveyor determined the Laboratory Director (LD) failed to ensure systems and processes were implemented and maintained effectively to identify errors and take corrective actions, when necessary. This affected the survey review period of September 13, 2018 - June 15, 2021. This is a repeat deficiency. The findings include: 1. The LD failed to ensure proficiency testing results were released and reported to HHS (Health and Human Services) to assure CLIA (Clinical Laboratory Improvement Amendments) was able to determine the laboratory's performance with proficiency testing. This affected the survey review period from September 13, 2018 - June 15, 2021. Refer to D2005. 2. The LD failed to ensure the technical staff verified the accuracy of "direct bilirubin" testing, at least twice annually. The laboratory routinely participated in organized proficiency testing for Chemistry, specifically "direct bilirubin" testing, which was not offered by the proficiency testing provider used, according to the TC. This affected seven testing events, reviewed by the surveyor. Refer to D5217. 3. The LD failed to ensure the technical staff implemented and document corrective actions for proficiency testing scores of less than one hundred percent and failing scores. This affected eight of eight proficiency testing events, reviewed by the surveyor. Refer to D5221. 4. During an interview on June 15, 2021 at

	4:02 PM, the surveyor inquired of the TC what monitoring the laboratory staff performed for quality assurance. The TC stated, when necessary, she met with the LD do discuss the laboratory. However, no real discussions regarding technical issues occurred nor was documented (Quality Assurance). When asked if the laboratory performed chart reviews, the TC stated that every patient requisition is checked against the EMR (Electronic Medical Record) for correct patient, ordering physician, test(s) done (The results which are interfaced are not verified in the EMR). This is done by the secretary. The TC added that the laboratory once verified medical charts for reporting accuracy, but had not done so in 4 to 5 years. The surveyor discussed with the TC the need for the laboratory to establish and implement a Quality Assurance Program to ensure monitoring of the pre-analytic, analytic and post-analytic systems of the laboratory.