

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0641797	<b>(X3) Date Survey Completed</b>  09/13/2018
<b>Name of Provider or Supplier</b>  Internal Medicine Associates	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on interviews with the Technical Consultant (TC), and a review of proficiency testing records and an order confirmation sheet, the surveyor determined the laboratory failed to enroll in proficiency testing for Coagulation [Prothrombin and INR (International Normalized Ratio)] for 2018. The laboratory continued to perform Coagulation testing on patient specimens. The laboratory did not establish an alternate method of verifying the accuracy of the testing, although no specimens were available through organized providers for the instrument and methodology used by the laboratory. This affected 2018 enrollment from January to September. The findings include: 1. During the initial tour of the laboratory at 9:44 AM on 9/12/18, the TC [also Testing Personnel #1 (TP #1)] stated the laboratory was performing Coagulation testing on the Hemochron Jr. The TC explained the instrument/methodology was not supported by any proficiency testing provider. Thus, the laboratory was not currently enrolled in proficiency testing for this testing (this same instrument was used for testing during the previous survey period). According to the TC, the laboratory had used AAFP for 2016 and 2017; however this provider no longer provided samples for this instrument-methodology type. The laboratory enrolled with AAB (American Association of Bioanalysts) for 2018; however no Coagulation samples were available</p>

for this instrument-methodology. The laboratory had not established an alternate method to verify the accuracy of the Coagulation testing. 2. The AAB proficiency testing records and a 2018 AAB Order Confirmation sheet (dated 4/04/18) failed to include Coagulation testing samples. 3. At 11:22 AM on 9/12/18, the TC stated the laboratory changed PT (Proficiency Testing) providers for 2018 from AAFP to AAB. According to the TC, the laboratory's enrollment should have been submitted through the McKesson representative in December of 2017. It was not until March of 2018, did the TC realize she had not received any PT specimens. Upon contacting AAB in March, the TC realized the laboratory had not been enrolled in any proficiency testing. On April 18, 2018, the laboratory received a late shipment of testing specimens for Chemistry (only 4 specimens) and CBCs (Complete Blood Counts). No PT samples were received for Coagulation.

**D2007**

**TESTING OF PROFICIENCY TESTING SAMPLES**  
CFR(s): 493.801(b)(1)

The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

This STANDARD is not met as evidenced by:  
Based on a review of the test menu, a review of proficiency testing records (attestation statements and instrument printouts), a review of personnel competency evaluations, and an interview with the Technical Consultant [also Testing Personnel (TP) #1], the surveyor determined the laboratory failed to rotate the testing of proficiency specimens among all testing personnel, who routinely perform moderate-complexity testing of patient specimens. This affected seven of seven testing events reviewed by the surveyor. The findings include: 1. The surveyor reviewed the testing menu with the Technical Consultant, upon initial tour of the laboratory on 9/12/18 at 9:44 AM. The testing menu included Hematology (Emerald Cell-Dyn, Complete Blood Count), Streck Auto Plus (Erythrocyte Sedimentation Rate), Coagulation (Hemochron Jr, PT /INR), and Chemistry/Endocrinology (Architect Plus), all moderate-complexity testing. 2. A review of the attestation statements retained with proficiency testing records revealed the testing personnel as TP #1 [also the Technical Consultant (TC)] for Events: AAFP 2016 B and C; and AAFP 2017 A, B and C. 3. There were no attestation statements retained for AAB Events for 2018 Quarters 1 and 2. However, the instrument printouts for Quarter 1 indicated TP #1 (TC) was the testing personnel. 4. In an interview on 9/12/18 at 11:45 AM, TP #1 stated she was the testing personnel for proficiency testing for Quarter 2. At 2:37 PM, TP #1 (TC) stated she understood proficiency testing should be rotated among the testing personnel. The TC also stated she usually performed all of the proficiency testing. The TC further stated TP #2 was trained and qualified to test all moderate-complexity testing as listed, and routinely tested patient specimens. 5. The CMS form 209 included TP #2 as a qualified testing personnel of moderate complexity testing. 6. TP #2's personnel competency assessments were last documented on 9/30/17 and 1/28/16, which indicated her competency to perform moderate complexity testing.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of personnel competency evaluations and an interview with the Technical Consultant (TC), [also Testing Personnel (TP) #1], the surveyor determined the laboratory failed to assess the competency of the TC for the CLIA survey review period of August 18, 2016 - September 12, 2018. This affected 1 of 2 testing personnel, who performed moderate complexity testing, and the only technical consultant, listed on the form CMS 209. The findings include: 1. A review of competency evaluations for the laboratory staff revealed no laboratory competency evaluation for TP #1, also the Technical Consultant. TP #1 was one of two testing personnel with greater than one year employment with the laboratory. 2. At the time of this review, at 10:05 AM on 9/12/18, the Technical Consultant stated the Laboratory Director had performed a Performance Evaluation (reviewed by the surveyor) on her (TP #1/TC); however confirmed this evaluation did not include laboratory responsibilities nor competency. At this time, the surveyor discussed with the TC ways to achieve this assessment with the Laboratory Director's involvement.

**D5213**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of 2016 and 2017 proficiency testing (PT) records and an interview with the Technical Consultant (TC), the surveyor determined the laboratory failed to ensure the accuracy of the Coagulation testing [Prothrombin and INR (International Normalized Ratio)], as evidenced by the laboratory failing to review and evaluate proficiency testing results, which were not graded by the PT provider. This affected five of five events (2016 - 2017), reviewed by the surveyor. The findings include: 1. A review of the AAFP (American Academy of Family Physicians) proficiency testing records for 2016 - 2017 revealed the results of the following events were not graded by AAFP, due to having no comparison group: AAFP 2016 B and C events; and AAFP 2017 A, B and C events. 2. On 9/12/18 at 2:08 PM, the TC confirmed the results were not graded by AAFP. Also, the TC did not provide documentation the laboratory staff reviewed the results for reporting accuracy.

**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 AAFP (American Academy of Family Physicians) proficiency testing records for 2017 and AAB (American Association of Bioanalysts) records for 2018, and an interview with the Technical Consultant (also Testing Personnel #1), the surveyor determined the laboratory failed to implement and document corrective actions for proficiency testing scores of less than one hundred percent (100 %), as

well as failed analyte scores. The laboratory further failed to provide documentation of self-evaluations for events, which for various reasons, were not evaluated by the proficiency testing providers. This affected Hematology and Chemistry testing for five of seven testing events. The findings include: 1. A review of the AAFP proficiency testing records for 2017 revealed the following scores for the laboratory: a) AAFP - 2016 B; Chemistry, Total Protein = 80 % b) AAFP - 2016 C; Hematology, Platelets = 60 % and RDW (Red Cell Distribution Width) = 80 % c) AAFP - 2017 A; Chemistry, Triglycerides = 80 % d) AAB Qtr 1 - 2018 ; Chemistry, Total bili = 50 % [This score was assessed on-site, by the Technical Consultant (TC) during the survey]. This event was tested in April of 2018. e) The Hematology portion of Event AAB Qtr 1 - 2018 was self evaluated, according to the TC at 11:50 AM; however the staff provided no documentation of the expected results from AAB nor a review and evaluation of the results. This event was tested in April of 2018. f) AAB Qtr 2 - 2018; Chemistry, HDL (High Density Lipoprotein) = 80 % g) AAB Qtr 2 - 2018 ; Hematology, WBC (White Blood Cell Count), Hemoglobin, Hematocrit and Platelets = 60 % and RBC (Red Blood Cell Count) = 80%; WBC Differential = less than 10 % accurate (lymphocytes and Granulocytes = 0 % and Monocytes = 20 %). 2. In an interview at 11:22 AM on 9/12/18, the Technical Consultant stated the specimens from Qtr. 1 2018 event were received and tested in April, 2018, due to difficulties with enrollment with AAB. According to the TC, due to the delay in enrollment and receipt of test specimens, a representative from AAB advised the laboratory staff to self-evaluate test results, which the laboratory failed to provide documentation. When asked what corrective actions had been taken for the Total Bilirubin score of 50 % (noted by the TC during the survey), the TC stated she did not think anything had been done with the failing score. 3. In an interview at 11:45 AM on 9/12/18, the TC explained the failures for proficiency testing AAB Qtr 2 - 2018 were due to grading based on an incorrect testing module (the laboratory was graded based on module D, instead of module A). A review of the Hematology result sheet for this event indicated no method code was provided. The TC further stated she probably failed to change the default code when she entered the results via on-line submission. The TC further explained she would be requesting AAB to provide a corrected report based on the correct testing module. 4. During an interview at 2:08 PM on 9/12/18, the above noted issues were reviewed and discussed with the TC, who confirmed missing documentation of evaluations and lack of documentation of corrective actions taken.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on a review of Hematology calibration records and an interview with the Technical Consultant [also Testing Personnel (TP) #1], the surveyor determined the

laboratory failed to calibrate the Emerald Cell-Dyn at least every six months as indicated as the policy per the Technical Consultant (TC). This affected one calibration for the time period between January, 2017 - April , 2018. The findings include: 1. A review of the 2016 - 2018 calibration records for the Emerald Cell-Dyn revealed calibrations, dated 1/19/17, 7/18/17 and 4/11/218 (a nine months timeframe), exceeding the every six-month time-frame, as per the laboratory's usual practice. 2. At 1:46 PM on 9/12/18, the Technical Consultant reviewed the instrument's calibration manual and stated it was possible she missed performing the calibration until April of 2018. At 2:35 PM, the TC confirmed the calibration was a little late, as the laboratory usually calibrates the Hematology analyzer every 6 months.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the Chemistry policy and procedure manual, a review of the calibration verification records, and an interview with the Technical Consultant (TC), also Testing Personnel #1, the surveyor determined the laboratory failed to perform calibration verifications at least every six months on the Chemistry/Endocrinology analytes tested on the Architect Plus. The findings include: 1. A review of the Chemistry policy and procedure manual, signed by the Laboratory Director on 8/24/12, revealed instructions to perform calibration verifications every six months on analytes with less than three routine calibrators. According to these instructions, this included Routine Chemistry analytes, Free Thyroxine (Free T4), Thyroid-Stimulating Hormone (TSH), and Total Prostate-Specific Antigen (TPSA). 2. A review of the calibration verification records for the Architect Plus (used for Chemistry and Endocrinology testing) revealed: a) On 8/24/16, the calibration verification for Hemoglobin A1c was performed. The laboratory failed to provide documentation of calibration verification, since 8/24/16. b) On 9/07/16, calibration verifications were performed for routine Chemistry analytes, excluding Hemoglobin A1c and Endocrinology analytes and TPSA. The calibrations were not verified again until 4/04/18, excluding Endocrinology analytes, Hemoglobin A1c, and TPSA. The laboratory

failed to provide documentation the calibration verifications were performed in 2017. c) On 6/22/17, vitamin D was performed, but not required, according to the TC. d) On 4/19/18, the calibration verifications for TPSA and TSH were performed. 3. In an interview on 9/12/18 at 2:35 PM, the TC reviewed the records and confirmed calibration verifications had not been performed at least every 6 months for all analytes requiring calibration verifications. The TC also added the policy needed to be updated as Vitamin D, Vitamin B12 and Free T4 did not require a calibration verification. The surveyor discussed establishing a schedule for the calibration verifications for the analytes to occur on or around the same dates to avoid confusion. The surveyor and TC also discussed difficulty performing TC duties, as well as being one of only two laboratory testing personnel, without any support assistance.

**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 interviews with the Technical Consultant (TC), a review of policy and procedure manuals, a review of competency evaluations, a review of proficiency testing records, calibration records and calibration verification records, the surveyor determined the Laboratory Director failed to ensure systems and processes were maintained to assure the laboratory provided quality laboratory services: 1. The LD failed to ensure the laboratory was enrolled in proficiency testing for Coagulation testing for 2018, testing routinely performed on patient specimens. The LD further failed to ensure an alternate method of verifying the accuracy of Coagulation testing was established, when organized proficiency testing was not available. 2. The LD failed to ensure the competency of the TC was assessed and maintained for the survey review period of August 2016 - September 13, 2018. 3. The LD failed to ensure calibrations and calibration verifications were performed at least every six months, as per the laboratory's policies and procedures and practices. 4. The LD failed to ensure ungraded proficiency testing results were reviewed and evaluated to determine the laboratory's accuracy of reporting Coagulation results for 2016 - 2017. 5. The LD failed to ensure corrective actions were implemented and documented for proficiency testing scores of less than one-hundred percent. The findings include: 1. Refer to D2000 and D6021. 2. Refer to D6021, D6030 and D5209. 3. Refer to D6021, D5437 and D5439. 4. Refer to D5213 and D6021. 5. Refer to D5221.

**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 interviews with the Technical Consultant (TC), a review of policy and procedure manuals, a review of competency evaluations, a review of proficiency testing records, calibration records and calibration verification records, the surveyor determined the Laboratory Director failed to ensure systems and processes were maintained to assure the laboratory provided quality laboratory services: 1. The LD failed to ensure the laboratory was enrolled in proficiency testing for Coagulation testing for 2018, testing routinely performed on patient specimens. The LD further failed to ensure an alternate method of verifying the accuracy of Coagulation testing was established, when organized proficiency testing was not available. 2. The LD failed to ensure the competency of the TC was assessed and maintained for the survey review period of August 2016 - September 13, 2018. 3. The LD failed to ensure calibrations and calibration verifications were performed at least every six months, as per the laboratory's policies and procedures and practices. 4. The LD failed to ensure ungraded proficiency testing results were reviewed and evaluated to determine the laboratory's accuracy of reporting Coagulation results for 2016 - 2017. 5. The LD failed to ensure corrective actions were implemented and documented for proficiency testing scores of less than one-hundred percent. The findings include: 1. Refer to D2000. 2. Refer D5209 and D030. 3. Refer to D5437 and D5439. 4. Refer to D5213. 5. Refer to D5221.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on a review of personnel competency evaluations and an interview with the Technical Consultant (TC), [also Testing Personnel (TP) #1], the surveyor determined the Laboratory Director failed to ensure the TC/TP #1 maintained her competency for the CLIA survey review period of August 18, 2016 - September 12, 2018. This affected 1 of 2 testing personnel, who performed moderate complexity testing, and the only technical consultant, listed on the form CMS 209. The findings include: 1. Refer to D5209. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor