Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0987260	08/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Internal Medicine Associates	70 Plaza Drive, Pell City, 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
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 a review of the API (American Proficiency Institute) Proficiency Testing records, and an interview with Testing Personnel #1 (also the Quality Coordinator), the surveyor determined the laboratory failed proficiency testing for CK-MB Isoenzymes in the 2017-Event #3 and the 2018-Event #1 Chemistry surveys, resulting in "Initial Unsuccessful Performance" for this analyte. (Refer to D2096.) .
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) Proficiency Testing records, and an interview with Testing Personnel #1 (also the Quality Coordinator), the surveyor determined the laboratory failed proficiency testing for two consecutive testing events for CK-MB Isoenzymes in the 2017-Event #3 and the 2018-Event #1 Chemistry surveys, resulting in "Initial Unsuccessful Performance" for this analyte. The findings include: 1. A review of the API (American Proficiency Institute) Proficiency Testing records revealed the following failing scores for CK-MB Isoenzymes: A) 2017-Event #3: 40% B) 2018-Event #1: 20% 2. In an interview on 8/2/2018 at 8:30 AM, Testing Personnel #2 reviewed and confirmed the above noted findings. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the temperature/humidity records, environmental requirements for the Sysmex XP-300 Hematology analyzer as stated in the Operator's Manual, and an interview with Testing Personnel (TP) #2 (also the Quality Coordinator), the surveyor determined the laboratory failed to monitor and document room temperature and humidity within the satellite laboratory each day patient CBC (Complete Blood Count) testing for February thru April 2018. The findings include: 1. A review of the temperature/humidity records revealed logs for the Building 1 satellite laboratory for May-July 2018. Testing Personnel performed CBC testing at that location using the Sysmex XP-300 Hematology analyzer. 2. A review of the Sysmex XP-300 Instructions for Use manual on page 2-2 under "Installation" revealed, "...Use the instrument in places where ambient temperatures ranges between 15 degrees C (Celsius) and 30 degrees C...", and "...relative humidity ranges between 30 - 85%." 3. During an interview on 8/2/2018 at 10:45 AM, TP #2 was asked about the timeline for the laboratory relocation and the opening of the satellite laboratory. TP #2 explained the main laboratory was in Building 1 until November 2017, and then they moved to a larger space in Building 3. However, to accommodate physician still in Building 1, the laboratory reopened a "satellite lab", installed a new Sysmex XP-300, and began patient testing in February 2018. When asked if the laboratory had monitored the temperature and humidity to ensure the analyzer was operated within the environmental parameters specified by the manufacturer, TP #2 confirmed they had not implemented monitoring until May 2018. Thus the above noted finding were confirmed. .

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 reviews of the installation and calibration records for the Sysmex XP-300 Hematology analyzer (used in the Building 1 satellite lab for Complete Blood Count testing), the Sysmex XS-1000i records, and an interview with Testing Personnel (TP) #2 (also the Quality Coordinator), the laboratory failed to perform a calibration in April 2018 after the six-month expiration of the previous calibration, performed during the installation of the instrument. The findings include: 1. A review of records for the Sysmex XP-300 Hematology analyzer revealed the instrument was calibrated during the installation procedures on 10/26/2017. A review of the "Calibration Certificate" revealed the expiration date for the calibration was 4/24/2018, however there was no documentation of a second calibration until 7/22/2018. 2. A review of the records for the Sysmex XS-1000i Hematology analyzer (in the Building 3 main Laboratory) revealed Sysmex Technical Support had performed a calibration on the XS-1000i on 4/23/2018. 3. During an interview on 8/2/2018 at 9:30 AM, TP #2 was asked if the Sysmex Technician had also performed a calibration on the Sysmex XP-300 on 4/23/2018 when he was on site for the Sysmex XS-1000i maintenance. TP #2 reviewed the calibration records, and stated she did not know why the Sysmex tech had not performed the calibration on the XP-300 at the same time. She stated the XP-300 was not calibrated until 7/22/2018, thus confirming the above noted findings. .
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 reviews of the calibration and calibration verification (C-V) records for the Tosoh G8 and the Beckman Coulter AU 680 Chemistry analyzers, and an interview with Testing Personnel (TP) #2 (also the Quality Coordinator), the laboratory failed to perform and document calibration verifications every six months as required by the laboratory policy. The findings include: 1. A review of the calibration records for the Tosoh G8 analyzer (which performs Glycohemoglobin or Hemoglobin A1c testing) revealed the tests were calibrated using two calibrators. A review of the calibration records for the AU 680 Chemistry analyzer revealed all analytes were calibrated using kits with only one or two calibrators. Tests using less than three calibrators require a C-V every six months. 2. A review of the records for the Tosoh G8 revealed a C-V was performed on the following dates: A) 6/02/2016 (reviewed during the previous survey) B) 7/25/2017 (more than one year after the previous C-V) C) 6/25/2018 (eleven months after the previous C-V) 3. A review of the records for the AU 680 Chemistry analyzer revealed a C-V for all analytes was performed on the following dates: A) 10/17/2016 B) 10/18/2017 (one year after the previous C-V) C) 6/12/2018 (eight months after the previous C-V) 4. During an interview on 8/2/2018 at 9:25 AM, when asked how often a CV should be performed, TP #2 stated, "We are supposed to run a C-V every six months". TP #2 further explained some C-V's had been missed in 2017 due to a period with no Laboratory Manager, high employee turnover, and poorly organized records. Thus the above noted findings were substantiated. 5. This is a repeat deficiency. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor