Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2124642	08/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Internal Medicine Associates Llc	7201 Happy Hollow Road, Suite 101, Trussville, 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
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 reviews of the records for the two Biosite Triage analyzers (used for D-Dimer and Cardiac Profile testing), patient records, and an interview with the previous Technical Consultant, the surveyor determined the laboratory failed to ensure a complete validation of the manufacturer's performance specifications for precision was performed before patient testing began. The findings include: 1. A review of the installation procedures for the two Biosite Triage analyzers (Serial Numbers [SN] 78143 and 80897) revealed accuracy and reportable range were verified by running five samples from the Alere Total 5 Calibration Verification (C-V) kits on the D-Dimer and Cardiac Profile cartridges on each instrument on 8/29/2018. 2. A review of quality control (QC) records revealed two levels of QC for the above tests were run on 8/14/2019 on Triage SN78143, and on 8/29/2019 on Triage SN80897. Since the QC and C-V samples were only run once for each level, the surveyor was unable to determine how the laboratory verified the manufacturer's performance specifications for precision (reproducibility). 3. During an interview on 8/15/2019 from 11:10 to 11:20 AM, the previous Technical Consultant (listed on the "Laboratory Personnel Report" - Form CMS-209 for the 2017 recertification survey) reviewed the above

	records, and confirmed the laboratory had failed to verify precision for the Triages. The surveyor then asked when patient testing began; the Consultant answered "9/7 /2018". Thus, the above findings were confirmed. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Hematology quality control (QC) reports and the patient records, and an interview with the previous Technical Consultant, the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on two days in 2018. The findings include: 1. A review of the Sysmex Insight Report with the daily control values for the Sysmex XP-300 Hematology analyzer revealed no QC results for 3/30 /2018 or 4/10/2018. 2. During an interview on 8/15/2019 at 1:18 PM, the previous Technical Consultant (listed on the "Laboratory Personnel Report"-Form CMS-209 for the 2017 recertification survey) reviewed the Hematology records and confirmed the testing personnel had failed to perform QC on the above dates. The surveyor then asked if patient CBC's (Complete Blood Counts) were run; the Consultant stated 10 patient CBCs were run on 3/30/2018, and 21 CBC's on 4/10/2018. Thus, the above findings were confirmed. SURVEYOR ID #32558 Licensure & Certification Surveyor