Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2089476	(X3) Date Survey Completed 01/03/2020
Name of Provider or Supplier Birmingham Internal Medicine Associates Llc	**Street Address, City, State** 2834 Moody Parkway, Moody, 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
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 the Biosite Triage records, a review of testing specialties on the current and previous Form CMS-116, and an interview with Testing Personnel #2, the surveyor determined the Laboratory Director: (1) failed to ensure the laboratory validated the manufacturer's performance specifications for the Biosite Triage analyzer, before patient testing began, and (2) failed to ensure the laboratory notified the CLIA State Agency within three months of testing to include the Specialty of Chemistry on the Certificate of Compliance. The findings include: 1. During the initial tour of the laboratory with TP #2 on 1/3/2020 at approximately 10:15 AM, the surveyor confirmed the only non-waived specialties in which the laboratory tested was Hematology. TP#2 stated the laboratory had not added any new tests or analyzers since the previous survey. [Note: Hematology was the only specialty on the Form CMS-116 for the 2017 survey, and the 1/3/2020 survey.] 2. A review of laboratory records revealed quality control testing on the Triage Meter for Cardiac Profile (Troponin, Myoglobin and and the isoenzyme CK-MB) from 7/2 - 12/5/2019, and D-dimer from 8/1 - 12/16/2019. A review of the Procedure manual revealed a small manufacturer's booklet with a hand-written note signed by TP #1, "Biosite Triage taken out of use 12/31/19". 3. During an interview on 1/3/2020 from 3:00 to 3:15 PM with TP #2 (who was speaking to TP #1 via her cell phone), the surveyor asked if the

	laboratory had validated the manufacturer's performance specifications before the analyzer was used for patient testing. TP #2 provided the validation data, and stated they had begun using the analyzer in July 2019. 4. A review of the validation records revealed the laboratory had performed reportable range (linearity) studies on the Cardiac and D-dimer cartridges using the 5-level Triage Total 5 kit on 11/19/2019. The Laboratory Director reviewed and approved the validation on the same date. The surveyor stated the data validated the instrument's accuracy and reportable range, however there was no evidence precision was checked. 5. As the interview continued on 1/3/2020 the surveyor asked if the CLIA State Agency had been notified within three months of testing to include the Specialty of Chemistry on the Certificate of Compliance. TP #2 stated, "No." The surveyor then asked how many patient tests were performed on the Triage in 2019; the laboratory agreed to forward the information to the CLIA Office. 6. On 1/3/2020 at 4:45 PM, TP #1 forwarded an e-mail to the surveyor with the following patient test statistics: A) July 2019: 10 D-Dimers; 7 CK-MB; 5 Myoglobin; 6 Troponin B) August 2019: 17 D-Dimers; 6 CK-MB; 5 Myoglobin; 5 Troponin C) September 2019: 18 D-Dimers; 13 CK-MB; 10 Myoglobin; 14 Troponin D) October 2019: 13 D-Dimers; 18 CK-MB; 10 Myoglobin; 18 Troponin E) November 2019: 9 D-Dimers; 10 CK-MB; 5 Myoglobin; 10 Troponin F) December 2019: 10 D-Dimers; 6 CK-MB; 2 Myoglobin; 6 Troponin SURVEYOR ID# 32558 Licensure and Certification Surveyor