Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2089476	06/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Internal Medicine Associates Llc	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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the Quidel Triage Meter Quality Control (QC) records, a lack of QC manufacturer's assay sheets, and an interview with the Laboratory Manager, the laboratory failed to retain the manufacturer's assay information sheets for control materials for two and a half years from the last survey (01/03/2020) to the current survey (06/15/2022). The findings include: 1. A review of Quidel Triage Meter QC records revealed a log sheet documenting the following for Cardiac Panel [CK-MB (Creatine Kinase - MB) , Myoglobin, and Troponin I] and D-Dimer: a) QC lot number b) QC expiration date c) Cartridge lot number d) QC result value The QC records did not include the manufacturer's assay sheets or documentation of acceptable ranges for each QC lot number. 2. During an interview on 06/15/2022 at 11:30 AM, the Laboratory Manager confirmed the laboratory had not retained the manufacturer's assay sheets with acceptable QC ranges.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the Quidel Triage Meter Quality Control (QC) records, patient logs, and an interview with the Laboratory Consultant, the laboratory failed to perform controls each day of patient testing or implement an Individualized Quality Control Plan (IQCP) for the Triage Meter. This was noted from 06/24/2021 (when patient testing started) to 10/20/2021. The findings include: 1. A review of the Triage Meter QC records revealed the laboratory performed only monthly QC from 07/20 /2021 to 09/29/2021 on the D-Dimer and Cardiac Panel cartridges; however the laboratory failed to implement an IQCP (to allow for reduced frequency of QC performance) until 10/20/2021. 2. A review of patient testing on the Triage Meter revealed 39 patient Cardiac Panels and 26 patient D-Dimers were performed from 06 /24/2021 to 09/30/2021, with no record of QC each day of patient testing. 3. During an interview on 06/15/2022 at 11:15 AM, the Laboratory Consultant confirmed the IQCP for the Triage Meter was not signed and implemented until 10/20/2021.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records, a review of the Policy and Procedure Manual, and an interview with the Laboratory Consultant, the Technical Consultant failed to evaluate the performance of testing personnel at least semiannually during the first year of moderate-complexity patient testing. This was noted on one out of three testing personnel. The findings include: 1. A review of the testing personnel records revealed the initial training for Testing Personnel #3 was on 09/15/2021, however there was no documentation of the semiannual competency evaluation due in March 2022. 2. A review of the Policy and Procedure Manual under "Competency Evaluation for Personnel Performing Clinical Testing" revealed the following: "... Newly hired personnel or a current staff member who is learning a procedure for the first time must demonstrate competency in accordance with the following schedule: Initial training...Six months following the initial...Twelve months following the initial...". 3. During an interview on 06/15/2022 at 11:30 AM, the Laboratory Consultant confirmed there was no semiannual competency evaluation documented for Testing Personnel #3.