Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1034255	03/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Internal Medicine Associates, P C	7191 Cahaba Valley Road, Suite 300, Birmingham, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 charts, Triage Quality Control (QC) package insert, and an interview with the Technical Consultant (TC), the laboratory failed to document the corrective action when the freezer temperature was outside the manufacturer's specified range. The surveyor noted freezer temperatures were out of range for 68 days out of 24 months reviewed in 2024 and 2025. The findings include: 1. A review of the temperature charts revealed the following days freezer temperatures were recorded with no corrective action documented: A) 2024: December (21 days), November (7 days), September (7 days), and August (11 days), B) 2025: January (22 days). 2. A review of the package insert for the temperature requirements for the materials stored in the freezer revealed Triage QC material "Store ... -20 degrees Celsius." 3. The TC confirmed the above findings during the exit interview on 03-03-2026 at 1:21 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Triage Daily Device log maintenance records, Triage Individual Quality Control Plan (IQCP), and an interview with the Technical Consultant (TC), the Laboratory failed to perform and document daily maintenance on the Ddimer and Cardiac Triage analyzer as per the manufacturer's requirements. This was noted for 17 days of 23 days in January 2025. The findings include: 1. A review of the Triage maintenance records revealed no documentation of daily maintenance for 17 days in January 2025. 2. A further review of the Triage IQCP revealed, "...run daily QC device before patient testing." 2. During the exit interview on 3-3-26 at 1:21 PM, the TC confirmed the above findings.