Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D2124642	**(X3) Date Survey Completed** 01/07/2026
Name of Provider or Supplier Birmingham Internal Medicine Associates Llc	**Street Address, City, State** 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**
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 a review of the environmental records and an interview with the Technical Consultant (TC), the Laboratory failed to ensure humidity in the room in which the Sysmex XP 300 Hematology analyzer was operated was within the manufacturer's acceptable limits. Humidity was noted below acceptable ranges for 55 days from 2021 to 2023. The findings include: 1. A review of the Sysmex XP 300 Hematology temperature records revealed Humidity was outside the manufacturer's acceptable parameters (30-80%) for a total of 59 days as follows: A) January through April 2024; 30 days B) January through April and December 2025; 29 days 2. During an interview on 1/7/2026, at 12:34 PM, the Technical Consultant confirmed the above findings and stated for best laboratory practice the laboratory door being closed will correct the humidity.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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 and an interview with the Technical Consultant (TC), the TC failed to evaluate semi-annual competencies for Testing Personnel (TP) performing moderate complexity testing. This was noted for one of four new TP listed on the CMS-209 (Laboratory Personnel Report) in 2024. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the TC for the semi-annual competencies of TP# 1 for November 2024. 2. During an interview on 5/1/2024, at 11:03 AM, Testing Personnel #8 confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Technical Consultant (TC), the TC failed to ensure all testing personnel had documentation of annual competency assessments. The surveyor noted no documentation of the 2024 annual competency assessment for one of four testing personnel listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed Testing Personnel #4 annual competency evaluations performed on 5/12/2025. There was no documentation of a 2024 annual competency assessment. 2. During an interview on 1/7/2026, at 1:32 PM, the TC confirmed the above findings.