Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0683308	04/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Specialists	513 Brookwood Blvd, Suite 50, 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 Daily Temperature and Humidity logs, the Beckman Coulter (BC)AU480, Tosoh G8, and Clinitek Advantus analyzer manuals, the patient electronic records and an interview with the Testing Personnel 1 (TP1), the laboratory failed to document the corrective action when the Room Temperature (RT) and Humidity were outside the manufacturers' specified ranges. The surveyor noted RT was outside manufacturers' acceptable range for 10 of the 83 days reviewed in 2024 and the humidity was outside manufacturers' acceptable range for 65 of the 125 days reviewed in 2024 and 78 of the 122 days reviewed in 2025. The findings include: 1. A review of the RT and Humidity logs revealed the following days were outside the Beckman Coulter AU480 and Tosoh G8 manufacturers' acceptable ranges. Room Temperature (2024) A) January-March, 1 day B) October-December, 9 days Humidity (2024) A) January-March, 52 days B) October-December, 13 days Humidity (2025) A) January-March, 48 days B) October-December, 30 days 2. A review of the manufacturers' user manuals revealed the following RT and/or Humidity requirements when the analyzers are in operation. A) BC AU 480, RT (18-32 degrees Celsius), Humidity (40-80 percent) B) Tosoh G8, Humidity (40-80 percent) C) Clinitek Advantus, RT (18-30 degrees Celsius) 3. A review of the patient electronic history

	records revealed 18,689 patient tests were performed when the RT and Humidity were outside acceptable ranges in 2024-2025. 4. TP1 confirmed the above findings during the exit conference on 04-21-2026 at 3:47 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 reviews of the Abbott Cell-Dyn Emerald Hematology maintenance logs, and an interview with Testing Personnel 1 (TP1), the laboratory failed to document the monthly and semi-annual maintenances, as per manufacturer's instructions. The surveyor noted two of the twelve months and one of the semi-annual maintenances for 2024 had no evidence of documentation. The findings include: 1. A review of the Abbott Cell-Dyn Emerald maintenance logs revealed no documentation of the March and May 2024 maintenances. In addition, there was no documentation for the second semi-annual maintenance due around August 2024. 2. A further review of the Abbott Cell-Dyn Emerald maintenance logs revealed places to document the monthly bleach cleaning and semi-annual pistons lubrication. 3. TP1 confirmed the above findings during the exit conference on 04-21-2026 at 3:47 PM.