Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2104515	04/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dba Alabama Oncology	3670 Grandview Pkwy Suite 200, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory received failing scores for the Red Cell Distribution Width-Coefficient of Variation (RDW-CV) , a non-regulated test. The surveyor noted the laboratory failed two consecutive PT events out of six events reviewed in 2024-2025. The findings include: 1. A review of the 2024-2025 API PT records revealed the laboratory received unsuccessful scores for the RDW-CV during the following PT events. A) 2024 Hematology/Coagulation First Event was 0 percent. B) 2024 Hematology/Coagulation Second Event was 60 percent. 2. The TC confirmed the above findings during the exit conference on 04-02-2026 at 12:25 PM.
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 observations during the laboratory tour, a lack of the Room Temperature (RT) and Humidity logs for the Abbott i-STAT analyzer, a review of the manufacturer's environmental requirements, and an interview with Technical Consultant (TC), the laboratory failed to implement a mechanism to ensure the instrument was operated within the manufacturer's required environmental parameters for 22 of the 22 months reviewed from June 2024 through March 2026. The findings include: 1) During the laboratory tour on 04-02-2026 at 8:39 AM, the surveyor noticed the i-STAT unit was not on the charger where it was stored. An interview with the charge nurse revealed testing was performed in a different room. However, the testing personnel had not recorded the RT and humidity of the room where the i-STAT was in use. 2) A review of the Abbott i-STAT System Manual Update revealed the following manufacturer's environment requirements on page 14. A) Operating Temperature: 16-30C (61-86F) for i-STAT cartridge testing B) Relative Humidity: 10-90% non-condensing 3) The TC confirmed the above findings during the exit conference on 04-02-2026 at 12:25 PM.