Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0991726	12/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hematology - Oncology Of Alabama	513 Brookwood Boulevard Suite 275, Homewood, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Technical Consultant (TC), the Testing Personnel (TP) failed to sign the PT attestation statements for the specialty in Hematology. This was noted in four of the six events reviewed from 2024-2025. The findings include: 1. A review of the AAB-MLE PT records revealed no signature of the TP on PT attestation statements for the following surveys: a) Hematology 2024 M1 Event, b) Hematology 2024 M2 Event, c) Hematology 2025 M2 Event, d) Hematology 2025 M3 Event. 2. During the exit conference on 12-11-2025 at 12:30 PM, the TC confirmed the above findings.
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 environmental logs, the Sysmex XN-L Instrument General Information Guide, the Quality Control (QC) package insert, the patient testing electronic records and an interview the Technical Consultant (TC), the laboratory failed to document the temperatures and humidity on days when patient testing was performed. The surveyor noted no documentation for three of the 60 days reviewed in 2025. The findings include: 1. A review of the environmental logs revealed missing documentations of the room and humidity and refrigerator temperatures for the following days; a) June 13, 2025 b) July 11, 2025 c) October 3, 2025 2. A review of the Sysmex XN-L Analyzer Manual revealed on page 41 the following manufacturer instrument specifications for temperature and humidity. A) Operating environment Ambient temperature: 15 to 35C B) Relative humidity: 20 to 85% 3. A review of the XN-L Check Control Materials package insert revealed the follwoing instructions for storage and shelf life before and after opening. A) Storage and shelf life of unopened product. XN-L CHECK is to be stored in a dark place at 2-8 C. B) Storage and shelf life after first opening. Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored in a dark place at 2-8 C after being re-capped. 4) A review of the electronic records revealed 44 patients were tested when the room temperature and humidity and the refrigerator temperature were not documented. 4. The TC confirmed the above findings during the exit conference on 12-11-2025 at 12: 30 PM.