Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2104515	11/07/2019
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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of AAB (American Association of Bioanalysts) proficiency testing records and an interview with the laboratory supervisor (also testing personnel #1), the surveyor determined the laboratory staff failed to implement and document corrective actions for a platelet score of eighty percent (80%) received on Hematology Event #1, 2018. This affected one of six testing events reviewed by the surveyor. The findings include: 1. A review of the AAB proficiency testing records revealed the laboratory scored 80% for the platelet count on Hematology Event #1, 2018. The review and evaluation form was signed by the laboratory director and technical consultant; however no corrective actions were documented. 2. During the exit interview on November 7, 2019 at 3:45 PM, Testing Personnel (TP) #1 reviewed the proficiency testing records for the platelet count score and confirmed no corrective actions had been documented to indicate implementation for this score (80 %) of less than one hundred percent.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 test menu, a review of temperature records, a lack of documentation of humidity monitoring, and an interview with testing personnel (TP #9) of Flow Cytometry, the surveyor determined the laboratory failed to establish an acceptable humidity range for the lab room, where the cytometer is located, and monitor the humidity in the area. This affected one of two laboratory rooms and the Flow Cytometer. The findings include: 1. During the initial tour of the laboratory on November 7, 2019 at 9:35 AM - 10:00 AM, the surveyor toured two separate lab areas. One of the lab areas is dedicated to Flow Cytometry and houses a Beckman Coulter Navios cytometer and an Abbott Emerald Cell Dyn for performing White Blood Cell counts (not reported). 2. A review of the temperature and maintenance logs for Flow Cytometry revealed no documentation of humidity. 3. In an interview at 3:00 PM on November 7, 2019, the surveyor inquired if the area where Flow Cytometry was performed was humidity dependent. TP #9 confirmed humidity was not being monitored in the area and was not certain it was necessary to do so. The Technical Advisor from Neogenomics reviewed the procedure manuals and stated the relative humidity should less than eighty percent {The acceptable range for humidity was added to the laboratory charts and faxed to the State Agency on November 8, 2019}.