

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0936907	(X3) Date Survey Completed 07/26/2018
Name of Provider or Supplier Dba Alabama Oncology	Street Address, City, State 833 Princeton Avenue Sw, Pop Iii, Suite 105a, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the environmental records, the Abbott Cell Dyn Emerald Hematology analyzer Operator's Guide and an interview with Testing Personnel (TP #1), the surveyor determined the laboratory failed to monitor and document correct humidity readings in the room where Hematology testing was performed. The findings include: 1. A review of the Installation Environment section in the operator's manual for the Abbott Cell Dyn Emerald Hematology analyzer revealed the following on page 2-4, "...The following are environmental requirements: ...Maximum relative humidity 80% (percent) for temperatures up to 90 degrees F...". 2. A review of the January 2017 thru July 2018 temperature/humidity logs revealed testing personnel recorded 77% with no variation every day of patient testing during this one and a half year period. The Technical Consultant had documented her reviews on each of the logs. 3. During an interview on 7/26/2018 at 1:20 PM, TP #1 was asked if staff were recording the humidity correctly since the readings had not varied in the last year and a half. TP #1 showed the surveyor the device, and pointed to the reading of 77 degrees F (Fahrenheit) and 92%, indicating they were recording 77% as the daily humidity. The surveyor observed the device was a Fisher Scientific digital Thermometer / Hygrometer with the ability to display the maximum and minimum temperature and</p>

humidity. The device was currently set to display the maximum temperature and humidity. The surveyor then asked if staff were hitting the clear/reset button on the device each day so the current information would be displayed. TP #1 stated they had never been taught this step, and were just reading whatever was on the left side (77) and recording this number as the humidity. Thus the above noted findings were substantiated. [NOTE: The surveyor found no problems with the room temperature monitoring, since testing personnel had recorded the temperatures correctly from a display on the digital wall clock, not the Fisher Scientific device.] SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor