Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306320	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Auburn	2901 Corporate Park Drive, Opelika, 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) 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 room temperature logs, a lack of humidity records, a review of environmental requirements for the Abbott Cell Dyn Emerald Hematology analyzer, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to: 1) establish acceptable room temperature ranges as per manufacturer's requirements, 2) ensure the Hematology analyzer was operated within the established environmental parameter specified by Abbott, and 3) monitor and document room humidity in the area of operation since the previous survey on 1/6 /2017. The findings include: 1. A review of the Cell Dyn Emerald Operator's Manual on page 2-4 revealed, "Installation Environment The following are environmental requirements: ... Temperature range: 64 - 90 degrees F (Fahrenheit) ... Maximum relative humidity 80% (percent) for temperatures up 90 degrees F". 2. A review of the 2017-2018 environmental logs revealed the testing personnel recorded room temperature each day of patient testing, however the acceptable "Range" at the top of the log was "10-85%". The surveyor further noted temperatures were less than 64 degrees F (colder than the environmental requirements specified by the manufacturer) sixteen days in January 2018 with no documentation of corrective action. The records did not include any documentation of room humidity for 2017-2018. 3. During an interview on 1/17/2019 at approximately 1:30 PM, the surveyor confirmed with TP #1

	that the log with the "10-85 %" range were actually the room temperature charts. The surveyor and TP #1 then reviewed environmental requirements for operation in the Cell Dyn Emerald Operator's Manual on page 2-4. TP #1 reviewed and confirmed the low room temperatures documented in January 2018, and the need to document the acceptable ranges on the log so testing personnel would know when corrective actions were needed. The surveyor then asked if the laboratory had monitored and documented the room humidity. TP #1 stated the thermometer/hygrometer device had temperature and humidity readings, however the testing personnel had not been recording the values. Thus the above noted findings were confirmed. SURVEYOR ID #32558 CLIA Licensure and Certification Surveyor