

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2166119	(X3) Date Survey Completed 10/30/2019
Name of Provider or Supplier Heart Center Cardiology Pc, The	Street Address, City, State 121 N 20th Street Ste 20b, 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	<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 manufacturer's guidelines for the Alere Triage Meter, a review of the laboratory's policies and procedures, a review of temperature logs, a lack of documentation of humidity monitoring, and an interview with the testing personnel and technical consultant, the surveyor determined the laboratory failed to monitor and document humidity of the test environment, necessary for reliable and optimal operation of the test system. This affected two Alere Triage Meters in one laboratory space, from September 3, 2019 (when patient testing began) until the survey date. The findings include: 1. The policies and procedures [POCT (Point of Care Training) Guide] indicated room temperature, freezer and refrigerator temperatures and humidity should be recorded daily. 2. At 10:12 AM on 10/30/2019, after reviewing the temperature logs and not noticing any documentation of humidity, the surveyor inquired of Testing Personnel (TP) #2 if humidity was monitored. TP #2 stated staff had talked about monitoring humidity, but humidity was not being documented. At 10:14 AM, the surveyor discussed manufacturer requirements for environmental factors. TP #2 stated she believed the range was 10 - 85% (percent). TP #2 stated the laboratory has the monitoring device for humidity, but humidity was not documented. The technical consultant reviewed the manufacturer's guidelines; and stated there were no requirements for humidity for the cartridge use, but for Triage</p>

system use the manufacturer indicated a humidity range of 10 -85 % is acceptable. 3. The surveyor performed an on-line search of the manufacturer's requirements for environmental factors for the Triage Meter, on November 4, 2019. The environmental factors listed in the manufacturer operation specifications included the humidity range of 10 - 85 %.