

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D1094619	<b>(X3) Date Survey Completed</b>  08/16/2018
<b>Name of Provider or Supplier</b>  Baptist Eastpoint-Clinical Laboratory	<b>Street Address, City, State</b>  2400 Eastpoint Parkway, Suite 160, Louisville, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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 staff interview and record review on 07/26/2018, the facility failed to monitor and document the percent humidity for the laboratory where the testing was performed. Percent humidity was not recorded from July 8, 2016, through July 25, 2018. Findings include: Review of the Manufacturer's Operation Manuals for the Sysmex XN 1000 Hematology Analyzer and Roche Cobas Chemistry Analyzer revealed the operating range for percent humidity should be between thirty percent (30%) and eighty-five percent (85%). Review of the Maintenance Log, revealed there was no documented evidence the percent humidity had been monitored from September 29, 2016, through August 15, 2018. Testing personnel acknowledged in an interview on 08/16/2018 at 12:35 PM, the laboratory failed to have a system in place to ensure the percent humidity was monitored and documented daily in accordance with manufacturer's recommendation for the Sysmex XN 1000 Hematology Analyzer and Roche Cobas Chemistry Analyzer.</p>