

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0648454	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Hazelwood Center	Street Address, City, State 1800 Old Bluegrass Ave, Louisville, KY	
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 staff interview and record review on 09/20/2018, the laboratory failed to monitor and document the humidity of the laboratory where the testing was performed. Humidity was not recorded from September 27, 2016 through September 19, 2018 Findings include: The Manufacturer's operations manual for the ACT Diff CBC analyzer lists an operating range for humidity for the analyzer between twenty percent (20%) and eighty-five percent (85%). Review of Maintenance log revealed no documented evidence the humidity had been monitored from September 27, 2016 through September 19, 2018. Testing personnel acknowledged in an interview at 12: 10 PM on 09/20/2018, the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily.</p>