

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1034723	(X3) Date Survey Completed 10/16/2018
Name of Provider or Supplier Parkway Pediatrics Psc	Street Address, City, State 809 Meyers Baker Rd, London, 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 10/16/2018 at 09:38AM, the laboratory failed to monitor and document the humidity of the laboratory where the testing was performed. Humidity was not recorded from September 23, 2016 through October 15, 2018. Findings include: The Manufacturer's operations manual for the ACT-Diff 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 23, 2016 through October 15, 2018. Testing personnel acknowledged in an interview at 09:38 AM on October 16, 2018, the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily.</p>