

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1066183	(X3) Date Survey Completed 07/16/2018
Name of Provider or Supplier Fmc Urgent Care Llc	Street Address, City, State 2352 Bruce B Downs Blvd Ste 101, Wesley Chapel, FL	
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 interview with Testing Personnel #A and record review of temperature logs and the hematology analyzer instrument manual, the laboratory failed to document humidity for two out of two years reviewed (2016-2018). Findings Included: Review of maintenance records for 2016-2018 revealed that room humidity was not documented. Review of the hematology analyzer instrument manual revealed the room humidity should be less than 80%. On 07/16/18 at 12:00 PM, Testing Personnel #A stated that the laboratory did not know the room humidity should be documented and monitored.</p>