

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0698512	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Windermere Pediatrics Pa	Street Address, City, State 7635 Ashley Park Ct Ste 501, Orlando, 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
D0000	A recertification survey was conducted on September 30, 2021. Windermere Pediatrics clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory failed to record the humidity of the room where testing was performed from 09/30/2019 to 09/30/2021. Findings: Review of quality control documents showed there were no logs recording the humidity of the room where testing was performed. Review of the Horiba ABX Micros 60 User's Manual for the hematology instrument noted the maximum humidity of the room should be 80% (percent). On 09/30/2021 at 11:30 AM, the Laboratory Director stated they did not record the humidity in the room where testing was performed.</p>