

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0287051	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier McRoberts & Steiner Chartered D/B/A	Street Address, City, State 3365 Burns Rd Ste 100, Palm Beach Gardens, 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 April 30, 2024. McRoberts and Steiner Chartered DBA Children's Physicians 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 interview, record review of laboratory logs and review of the Beckman Coulter DxH 520 Instructions for Use manual, the laboratory failed to record the humidity of the laboratory from 01/13/2022 to 4/30/2024. Findings: Review of the Beckman Coulter DxH 520 Instructions for Use manual noted a maximum relative humidity rate of 80 %. Review of the laboratory's temperature logs showed the humidity of the laboratory was not recorded. On 04/30/2024 at 11:45 AM, Testing Personnel A acknowledged the humidity of the laboratory was not recorded.</p>