

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0693984	(X3) Date Survey Completed 11/20/2025
Name of Provider or Supplier Carolina Kids Pediatric Associates	Street Address, City, State 2605 Blue Ridge Road , Suite 100, Raleigh, NC	
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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the DxH500 manufacturer instructions, review of 2024 and 2025 humidity logs, and interview with Testing Personnel (TP) on 11/20/2025, the laboratory failed to establish a humidity range consistent with manufacturer requirements from 4/5/2024 to 11/20/2025. Findings: Review of the "Instructions for Use DxH500" section 1-7 revealed, "...Humidity...a maximum of 80% relative humidity..." Review of the "CAROLINA KIDS LABORATORY ROOM HUMIDITY LOG" for 2024 and 2025 revealed, "...RANGE: 20-85 percent." The laboratory does not meet the required manufacturer range "...a maximum of 80% relative humidity..." for the DXH500 analyzer. During interview at approximately 1:18 p.m., TP #1 confirmed the humidity range does not meet manufacturer requirements.</p>