

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0981717	(X3) Date Survey Completed 07/03/2025
Name of Provider or Supplier Medical Park Family Care	Street Address, City, State 1034 South Tallassee Street, Dadeville, AL	
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 reviews of the environmental logs, Sysmex XP-300 Instructions For Use (IFU) manual, and an interview with the Technical Consultant (TC), the laboratory failed to ensure and document corrective action when the humidity in the room where the analyzer was operated were outside the manufacturer's acceptable limits. The surveyor noted the humidity were out-of-range for 7 out of 31 days in January 2025. The findings include: 1. A review of the environmental logs revealed the humidity had no corrective actions documented when it was outside the manufacturer's acceptable limits for the following days. a) January 2 and 3, 2025, humidity was 27 percent b) January 5, 2025, humidity was 27 percent c) January 16, 2025, humidity was 28 percent d) January 17, 2025, humidity was 19 percent e) January 18, 2025, humidity was 21 percent f) January 22, 2025, humidity was 20 percent 2. A review of the Sysmex XP-300 IFU manual revealed under Technical Information, page 14-1, the manufacturer's required operating environment for humidity, "Relative Humidity: 30-85 percent". 3. The TC confirmed the above findings during the exit conference on 07-03-2025 at 11:20 AM.</p>