

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2148957	(X3) Date Survey Completed 02/10/2023
Name of Provider or Supplier Kids Clinic	Street Address, City, State 119 Stephen J White Memorial Blvd, Talladega, 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>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 a review of the environmental records and an interview with Testing Personnel #1, the Laboratory failed to ensure humidity in the room in which the Sysmex XP 300 Hematology analyzer was operated was within the manufacturer's acceptable limits. Humidity was noted below acceptable ranges for 55 days from 2021 to 2023. The findings include: 1. A review of the Sysmex XP 300 Hematology temperature records revealed Humidity was below the manufacturer's acceptable parameters (30-85%) for a total of 55 days as follows: A) November and December 2021; 8 days B) January through March and October through December 2022; 44 days C) January 2023; 3 days 2. During an interview on February 10, 2023, at 12:05 PM, Testing Personnel #1 confirmed the above findings.</p>