

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2320463	(X3) Date Survey Completed 10/01/2025
Name of Provider or Supplier Helms Healthcare, Inc	Street Address, City, State 131 Florey Street, Vincent, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on a review of the temperature records, the Sysmex XN 330 user manual, and an interview with the Technical Consultant (TC), the Laboratory failed to document Humidity for the room in which Sysmex XN 330 was stored. This was noted for 59 days of 5 months reviewed in 2025. The findings include: 1. A review of the temperature records revealed the laboratory failed to document Humidity for the room in which the Sysmex XN 330 Hematology analyzer was stored for the following months: a) May 2025: 10 days. b) June 2025: 21 days. c) July 2025: 23 days. d) August 2025: 3 days. e) September 2025: 2 days. 2. A further review of the Sysmex XN 330 user manual revealed, "Relative humidity should be within the range of 20-85%." 3. During an interview on 10-1-2025, at 12:35 PM, the TC confirmed the above findings.