Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1085608	(X3) Date Survey Completed 08/17/2023
Name of Provider or Supplier White River Medical Center	**Street Address, City, State** 1710 Harrison Street, Batesville, AR	

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) 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. This STANDARD is not met as evidenced by: Based on review of policy and procedure manuals, manufacturer's instruction, temperature logs, and interview with staff, the laboratory failed to follow manufacturer's instructions for operational environment relative humidity for Sysmex XN-2000 and Stago Compact Max. Findings follow: A) Review of the Sysmex XN-2000 Instruction for use revealed the operating environment for relative humidity is "20 to 85% ". B) Review of the Stago Compact Max reference manual revealed the operation conditions is "Relative humidity: 20% to 80% without condensation ". C) Review of the Chemistry Refrigerator/Freezer Temperature Check Sheet log for July 2023 through May 2022 revealed 24 days out 426 days humidity below 20%. D) During an interview on 8/17/2023 at 11:15 a.m. the laboratory staff member General Supervisor - 2 (GS-2) confirmed the 24 days below 20% hunidity.