Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 33D0939484	**(X3) Date Survey Completed** 07/25/2023
Name of Provider or Supplier Crystal Run Healthcare Physicians Llp	**Street Address, City, State** 2 Centerock Road, West Nyack, NY	
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 the review of the Beckman Coulter's AU680 manufacturer's requirements, relative humidity (RH) records, and interviews with the laboratory supervisor and testing personnel, the laboratory failed to document accurate RH readings where reagent storage and patient testing occurred. Findings: 1. The Beckman Coulter AU680 analyzer required RH of 20% - 80%. The RH was out of range for the following dates: January 2022 for 31 days; February 2022 for 28 days; March 2022 for 31 days; April 2022 for 29 days; May 2022 for 30 days; June 2022 for 30 days; July 2022 for 31 days; and August 2022 for 15 days. 2. Confirmed the findings by interview with testing personnel on July 25, 2023, at approximately 2:15 P.M. 3. Confirmed by interview with the supervisor that a new thermometer for temperature /RH was purchased and installed on August 16, 2022.