

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2153992	(X3) Date Survey Completed 08/14/2024
Name of Provider or Supplier Rm Lab DbA Express Lab Woodruff	Street Address, City, State 2001 S Woodruff Ave Ste 15b, Idaho Falls, ID	
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 temperature records, patient records and an interview with the laboratory director on 8/14/2024, the laboratory failed to document temperatures and humidity as required for operation of the Sysmex XN-330 in 2023 and 2024. The findings include: 1. A review of the user manual for the Sysmex XN-330 identified an operational temperature of 15-35 C and an operational humidity of 20-80%. 2. A random review of the laboratory's daily temperature records identified that the laboratory failed to document room and refrigerator temperatures and humidity on 7 /10/2023 and 2/26/2024. 3. A review of patient records identified four (4) patients (3209141, 3209148, 3209328, 3209891) that had complete blood count (CBC) testing performed on 7/10/2023 and two (2) patients (3408880, 3409025) that had CBC testing performed on 2/26/2024. 4. An interview with the laboratory director on 8/14 /2024 at 10:32 am confirmed that the laboratory fail to document temperatures and humidity on the above testing days. 5. The laboratory reports performing 1245 CBC tests annually.</p>