

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2247841	(X3) Date Survey Completed 01/23/2024
Name of Provider or Supplier Cerflux, Inc	Street Address, City, State 215 Richard Arrington Jr Blvd N #101, Birmingham, 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 incubator temperature records, policy and procedures manual, and an interview with the Laboratory Director, the Laboratory failed to document temperatures for the incubator. This was noted for four out of four months reviewed. The findings include: 1. A review of the temperature records revealed a lack of documented temperatures for the incubator from the date patient testing began on 9/18/2023 to 1/23/2024. 2. A further review of the policy and procedures manual revealed, "It is constructed to maintain a temperature of 35-37 degrees Celsius... temperatures will be checked and recorded on the temperature chart each day that the lab is open." 3. During an interview on January 23rd, 2024, at 12:19 PM, the Laboratory Director confirmed the above findings.</p>