

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0990132	(X3) Date Survey Completed 06/04/2026
Name of Provider or Supplier Leonid Sorkin, Md	Street Address, City, State 2829 Ocean Parkway Suite C, Brooklyn, 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) (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 lack of temperature records, review of Standard Operating Procedures (SOPs) and analyzer manufacturer's instructions, as well as interview with the Technical Consultant (TC), the laboratory failed to monitor and document analyzer temperature to ensure accurate and reliable test system operation and test result reporting. FINDINGS: 1. There was no documentation of BD Affirm VPIII Microbial Identification System analyzer lysis block temperature for January 2026. 2. This is contrary to instructions included in the S&R We Care Medical, PC SOPs which indicate analyzer lysis block temperature monitoring and documentation. 3. The BD Affirm VPIII Microbial Identification System analyzer manufacturer's instructions specified patient specimen lysis block operating temperature range of 855C. 4. Approximately sixty-five patient specimens were tested in January 2026. 5. The TC confirmed the findings on June 4, 2026, at 1:00 P.M.