Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2272082	08/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Staten Island Reproductive Medicine Llc	1441 South Avenue Suite 204, Staten Island, 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 direct observation, review of test kit manufacturer's Quality Control (QC) specifications and Standard Operating Procedures (SOPs), lack of temperature records, as well as interview with the Laboratory Director (LD), the laboratory failed to monitor and document laboratory room temperature. FINDINGS: 1. There was no documentation of temperature monitoring in the laboratory area where the QC kit storage and patient specimen processing, testing occurred. 2. The Accu-Beads QC manufacturer's specifications indicated "Room Temperature" kit storage. 3. The current, approved SOPs did not include instructions for performing laboratory room temperature monitoring and documentation. 4. Approximately 240 patients were tested during the respective survey period. 5. The LD confirmed the findings on August 27, 2025, at 11:00 A.M.