Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0683891	02/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Fred Grunseid, Md Pc	1687 Ralph Avenue, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the current, approved standard operating procedures and direct observation of refrigerator inventory, the laboratory failed to comply with the facility's safety and universal precautions protocol. FINDINGS: 1. On February 1, 2024, 9:45 A.M., the surveyor observed food, beverages stored among Coulter control reagents, Quantimetrix Dropper urine control, several vaccines, and patient blood specimens in the laboratory's refrigerator. 2. This is contrary to instructions indicated in the current, approved safety and universal precautions standard operating procedure.
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 review of thermometer manufacturer's instructions, direct observation of laboratory's room and refrigerator thermometers, lack of calibration records, as well as interview with the testing person (TP), the laboratory failed to perform and document thermometer calibrations. FINDINGS: 1. The thermometer manufacturer's instructions require biannual calibration of thermometers utilized for patient specimen and processing reagent storage temperature monitoring. 2. There was no documentation of Traceable Digital (S/N 160699539) thermometer calibration. 3. There was no documentation of refrigerator thermometer certification. 4. The TP confirmed the findings on February 1, 2024, at approximately 9:45 A.M.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter AcT Diff hematology analyzer standard operating procedures, quality control records, and interview with the TP, the laboratory failed to perform and document the required Beckman Coulter AcT Diff analyzer six-month calibration. FINDINGS: 1. The most recent documented calibration of the Beckman Coulter AcT Diff hematology analyzer was April 24, 2022. 2. The Beckman Coulter AcT Diff 2 hematology analyzer was not calibrated from October 24, 2022, through the survey date. a. Approximately 16,000 patient specimens were processed and results reported from October 24, 2022, through the survey date. 3. This is contrary to instructions indicated in the Beckman Coulter AcT Diff hematology analyzer manufacturer's requirements as well as current, approved laboratory standard operating procedures which require hematology analyzer calibration to be performed every six months and as needed for preventative maintenance. 4. The TP confirmed the findings on February 1, 2024, at approximately 10:30 A.M.