Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0150014	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
David L Hurwitz Md	147-15 70th Rd, Flushing, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the package inserts for Quidel Sofia Covid Sars, Seksui OSOM Rapid Strep A, Consult Diagnostics for Influenza A & B, lack of Quality Control (QC) records, and interview via phone the waived testing person, the laboratory failed to follow the QC requirements for the following test kits: Quidel Sofia Covid, Seksui OSOM Rapid Strep A, and Consult Diagnostics for Influenza Flu A & B. FINDINGS: 1. The laboratory performed Quidel Sofia Covid 19 testing from 12/30/2021 through 1 /22/2022. During this time, 113 patients were tested and results were reported. Also during this time, QC was not performed for six kits and there was no documentation of lot numbers and expiration dates. a. Quidel Sofia Covid manufacturer's requirements indicated that QC materials included with the kits were to be utilized for each new kit and/or shipment. 2. Manufacturer's requirements for Seksui OSOM Rapid Strep A(RST) and Consult Diagnostics for Influenza A & B required that QC materials included with the kits were to be utilized for each new kit and/or shipment. a. The laboratory failed to document kit lot numbers and expiration dates utilized therefore it was not possible to determine how many testing kits were utilized from 12 /30/2021 through the survey date. b. Seksui OSOM Rapid Strep A; lot# 231065, expiration date 07/31/2024; and Consult Diagnostics for Influenza A & B, lot # 442M21, expiration date 12/31/2024 were in use at the time of the survey. c. Approximately 1,741 patients were tested for RST and Influenza from 12/30/2021 through the survey date.
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 the laboratory's throat culture procedure, lack of incubator temperature documentation, and an interview via phone with the testing person, the laboratory failed to record the incubator temperatures from 12/31/2021 through the survey date. FINDINGS: 1. Throat culture procedures performed with SSA & 0.04 bacitracin required incubation temperatures of 37O C +/- 5 for 12- 24 hours. 2. The laboratory failed to document incubator temperatures from 12/30/2021 through the survey date.