Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1106919	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
New Vision Medical Diagnostic ,Llc	Urb Hermanas Davila J-23 Ave Betances, Bayamon, PR	

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) 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 ImmunoCard Mycoplasma manufacturer's instructions, Mycoplasma pneumoniae testing records review (years 2023-2024), and laboratory director interview on April 24, 2024, at 1:07 P.M., it was determined that the laboratory failed to follow the manufacturer's instruction regarding to the established temperature range for Mycoplasma pneumoniae when 195 out of 1924 patient's specimens were processed and reported for Mycoplasma pneumoniae from January 2, 2023, to April 23,2024. The findings include: 1. The laboratory uses the ImmunoCard Mycoplasma Test Kit to perform the Mycoplasma pneumoniae qualitative tests. (Reviewed on April 24,2024 at 1:07 P.M.) 2. On April 24,2024 at 1:10 P.M., the ImmunoCard Mycoplasma manufacturer's instructions were reviewed. The manufacturer's instructions established to perform the Mycoplasma pneumoniae test procedures between 22C to 25 range temperature. 3. On April 24,2024 at 1:15 P.M., the Mycoplasma pneumoniae testing records review showed that the laboratory processed and reported 195 out of 1924 patient's specimens for Mycoplasma pneumoniae test from January 2,2023 to April 23,2024, with a temperature range within 17.8C to 21.7

	C 4. The laboratory director confirmed during interview on April 24,2024, at 1:25 P. M., that the laboratory processed patient's samples outside the established temperature range by the manufacturer.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and laboratory director interview on April 24,2024, at 2: 00 P.M., it was determined that the director did not assure that the manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test were followed, when the laboratory processed and reported 195 out of 1924 patient's specimens for Mycoplasma pneumoniae. Refer to D5413.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and laboratory director interview on April 24,2024, at 1: 40 P.M., it was determined that the testing personnel did not follow the manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test, when she processed 195 patient's specimens for Mycoplasma pneumoniae. Refer to D5413.