Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0673783	01/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sur -Med Medical Center, Corp	8 Colon Pacheco, Salinas, 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 pneumoniae (Meridian) manufacturer's instructions, Mycoplasma pneumoniae testing records review (years 2023-2024) and laboratory general supervisor interview on January 23, 2024 at 10:45 AM, it was determined that the laboratory failed to follow the manufacturer's instruction regarding to the established temperature range 365 out of 365 days when patient's specimens were tested and reported for Mycoplasma pneumoniae of year 2023. The findings include: 1. The laboratory uses ImmunoCard Mycoplasma (Meridian) to perform Mycoplasma patient's samples tests. (Reviewed on January 23, 2024 at 10:00 AM) 2. The ImmunoCard Mycoplasma (Meridian) manufacturer's instructions establish that the Mycoplasma test must be performed at room temperature between 22 C to 25 C. (Reviewed on January 23, 2024 at 10:10 AM) 3. On January 23, 2024 at 10:35 AM, the records of the Mycoplasma pneumoniae testing showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from from January 1, 2023 to December 31, 2023. 4.The laboratory general supervisor confirmed during an interview, on January 23,2024 at 10:45 AM, that the laboratory did not monitor nor document the room temperature when it processed the patient's specimens for Mycoplasma pneumoniae test. 5. The laboratory processed and reported 4978 out

	of 4978 patient's samples for Mycoplasma pneumoniae test from January 1, 2023 to December 31, 2023.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records (years 2023-2024) and laboratory general supervisor interview on January 23, 2024 at 10:45 AM, it was determined that the laboratory director did not assure that the manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test, when the laboratory processed and reported 4,978 out of 4,978 patient's specimens for Mycoplasma pneumoniae of year 2023. Refer to D5413.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and general supervisor interview on January 23, 2024 at 10:45 AM, it was determined that the general supervisor did not assure that the manufacturer's instructions were followed by the testing personnel regarding to temperature range for Mycoplasma pneumoniae test. Refer to D5413.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high 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 general supervisor interview on January 26, 2024 at 11:30 AM, it was determined that the testiing personnel failed to follow the manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test, when the laboratory processed and reported 4,978 out of 4,978 patient's specimens for Mycoplasma pneumoniae. Refer to D5413. .