Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658206	10/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Licer	Munoz Rivera No 5, San Lorenzo, 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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on ImmunoCard Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and laboratory director interview on October 5, 2023, at 1:18 PM; it was determined that the laboratory failed to follow the manufacturer's instruction when 16 out of 162 patient's specimens were tested for Immunocard Mycoplasma pneumoniae by Meridian Bioscience reagent kit from December 7, 2021, to July 12, 2023. The findings include: 1. The manufacturer's instructions establish to perform the test procedures between 22 to 25C. 2. On October 5,2023 at 1:18PM, the Mycoplasma pneumoniae testing records showed that the laboratory did not follow the manufacturer instructions when it processed the following patient's specimens: Testing Date Sample Id Temperature Processed 11/02 /2022 370272 21C 11/07/2022 370326 21C 11/28/2022 370482 21C 11/28/2022 370483 21C 11/28/2022 370486 21C 11/28/2022 370485 21C 11/29/2022 370495 21C 11/29/2022 370498 21C 12/05/2022 370550 21C 12/05/2022 370556 21C 01/04 /2023 370701 20C 01/04/2023 370705 20C 01/04/2023 370706 20C 01/05/2023 370713 20C 01/09/2023 370725 21C 01/11/2023 370764 20C 3. The laboratory director confirmed during interview on October 5,2023 at 1:35PM, that the laboratory did not follow the manufacturer's instructions related to temperature processing. 4. The laboratory processed and reported 16 out of 162 patient's specimens for Mycoplasma pneumoniae test out of the manufacturer's established temperature range from December 7,2021 to July 12,2023. 5. This deficiency was cited on September 17,2021.

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 laboratory room temperature and relative humidity daily log records review (years 2022-2023) and laboratory director interview on October 5, 2023, at 12:00 PM; it was determined that the laboratory failed to monitor the room temperature and relative humidity as established. The finding include: 1. The laboratory room temperature and relative humidity records were reviewed for the year 2022 and 2023. (Reviewed on October 5,2023 at 12:00 PM) 2. The room temperature and relative humidity log records,established that the room temperature and humidity must be documented every day. (Reviewed on October 5,2023 at 12:05 PM) must check and document it every day. (Reviewed on October 5,2023 at 12:05 PM) 3. The records showed that the room temperature and relative humidity were not monitored nor documented since August 4, 2023. (Reviewed on October 5,2023 at 12:07 PM) 4. The laboratory director confirmed on October 5,2023, at 12:10 PM, that the laboratory did not document the room temperature and relative humidity.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on microscopy urinalysis quality control records (years 2022-2023), microscopy urinalysis written procedure review, and laboratory director interview on October 5,2023, at 12:15 PM; it was determined that the laboratory failed to include two levels of control material, when the laboratory processed five (5) patient specimen for urinalysis sediment on October 3,2023. The findings include: 1. The laboratory used Clinitek 500 instrument to perform urinalysis patient samples. (Reviewed October 5,2023 at 12:15 PM) 2. Review of the microscopy urinalysis quality control records from August 1,2023 to October 5, 2023, showed that the laboratory did not include a positive and negative control material, at least each day of patient testing. (Reviewed October 5,2023 at 12:20 PM) 3. The laboratory director confirmed on October 5,2023 at 12:25 PM, that the laboratory did not include any control material for microscopy urinalysis. 4. The laboratory processed and reported

	five patient's tests for microscopic sediment urine on October 2, 2023. (Reviewed October 5, 2023, at 12:28 PM)
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 testing, laboratory room temperature and relative humidity, urinalysis quality control records and laboratory director interview on October 5,2023, at 2:30 PM it was determined that the director failed to met with the quality control procedures for Mycoplasma pneumoniae test, urinalysis microscopy test and monitor the laboratory room temperature and relative humidity. Refer to D5405, D5413 and D5445.