Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0873264	11/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Toledo	Del Parque No 352, San Juan, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an announced CLIA recertification survey at Laboratorio Clinico Toledo on November 12, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The laboratory was found out of compliance with the following conditions : D5008-42 C.F. R 493.1208 Condition : General Immunology D6000-42 C.F.R 493.1403 Condition Laboratory Director
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the Mycoplasma pneumoniae IgM quality control records (year 2024) and laboratory director interview on November 12, 2024 at 1:00 P.M., , it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae IgM test. Refer to D5449.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review (year 2023-2024) written policies for personel

	competency and laboratory director interview on November 12, 2024 at 10:20 A.M., it was determined that the laboratory failed to follow the established schedule for testing personnel (MT-8437) competence evaluation. The findings include: 1. The laboratory written policies stated that personnel competence evaluation must be performed every year. 2. During the survey performed on November 12, 2024 , the review of records showed that the competency of the testing personnel from the year 2023 was perform on September 3, 2024. 3. The laboratory director confirmed on November 12, 2024 at 1:00 P.M. that the laboratory failed to follow the established schedule for testing personnel (MT-8437) competence evaluation.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae test quality control records, patient results worksheet review; (years 2024) , laboratory testing personnel and laboratory director interview on November 12, 2024 at 1:00P.M., it was determined that the laboratory did not include an external positive and negative control material each day of use for Mycoplasma pneumoniae when 21 out of 32 patient specimen were processed and reported since february 9, 2024. The findings include: 1. The laboratory begin to test Mycoplasma pneumoniae test on January 24, 2024. 2. The Mycoplasma pneumoniae test quality control records were reviewed from february 9, 2024 to November 12, 2024. (reviewed on November 12, 2024 at 1:00 P.M.) 3. Review of Mycoplasma pneumoniae quality control records and patient results worksheet showed that the laboratory did not include any control material each day of patient testing during the following days: 5/25/24, 6/1/24, 6/15/24, 6/29/24, 7/13/24, 7/16/24, 7/24/24, 7/27/24, 9/10/24, 9/11/24, 9/12/24, 9/13/24, 9/14/24 and 9/19/24. 4. The laboratory processed and reported 21 Mycoplasma pneumoniae test those days. 5. The laboratory director confirmed on November 12, 2024 at 1:15 P.M, that the laboratory failed to include a negative and positive control material, each day of testing, when performed Mycoplasma pneumonia test.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of Mycoplasma pneumonae quality control records review (year 2024) on November 12, 2024 at 1:15 P.M.it was determined that the laboratory director failed to fulfill her responsibilities with the Mycoplasma pneumoniae analytic requirements. Refer to D6020.

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 IgM test quality control review (year 2024) , worksheet records review and laboratory director interview on November 12, 2024 at 1:30 P.M., it was determined that the laboratory director failed to fulfill his responsibilities to ensure compliance with the Mycoplasma pneumoniae IgM laboratory quality control requirements, when 21 patients were processed and reported from february 2024 to November 2024. Refer to D5449.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on personnel review files and laboratory director (LD) interview on November 12, 2024 at 10:20 A.M., it was found that the laboratory director did not ensure that the technical consultant competence procedures were establish. The findings include: 1. The medical technologist license # 8437 occupied the technical consultant position as stablished by the laboratory director. 2. Review of personnel files did not include any competence procedure for the technical consultant. The competence evaluation sheet showed during the survey did not include evaluation parameter for the technical consultant based on duties. 3. The LD stated on November 12, 2024 at 1:25 P.M. that the laboratory did not have written procedures for the technical consultant competency.