Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0710605	08/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Caribe	Munoz Rivera 35, Rincon, 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 unannounced CLIA Recertification survey at the Laboratorio Clnico Caribe, on August 26, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on August 26, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 General Immunology 42 CFR 493.1212 Endocrinology 42 CFR 493.1441 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 Mycoplasma pneumoniae quality control records, patient test worksheets review (2024 -2025), and interview with the laboratory general supervisor on August 26, 2025, at 10:50 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for Mycoplasma pneumoniae tests. Refer to D5449(A) The findings include: 1. The laboratory failed to include external positive and negative control material each day of patient testing.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, 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 Human Chorionic Gonadotropin (hCG) quality control records, patient test worksheets review (2024 - 2025), and interview with the laboratory general supervisor on August 26, 2025, at 10:25 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hCG tests. Refer to D5449(B) The findings include: 1. The laboratory failed to include an external positive and negative control material each day of patient testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: A. Based on Mycoplasma pneumoniae quality control records, patient test worksheets review (2024 - 2025), and interview with the laboratory general supervisor on August 26, 2025, at 10:50 AM, it was determined that the laboratory failed to include external positive and negative control material each day of patient testing, when processed and reported 252 out of 271 Mycoplasma pneumoniae patient specimens from March 20, 2024, to August 7, 2025. The findings include: 1. The laboratory used the Meridian Diagnostics ImmunoCard Mycoplasma to perform Mycoplasma pneumoniae on patient specimens. 2. Review of the Mycoplasma pneumoniae quality control records and patient test worksheets on August 26, 2025, at 10:50 AM, showed that the laboratory failed to include external positive and negative control material each day of patient testing. 3. The laboratory processed and reported 252 out of 271 Mycoplasma pneumoniae patient specimens from March 20, 2024, to August 7, 2025, without external controls. 4. On August 26, 2025, at 11:00 AM, the laboratory general supervisor confirmed that the laboratory did not include external positive and negative control material each day of patient testing. B. Based on the human Chorionic Gonadotropin (hCG) quality control records, patient test worksheets review (2024 - 2025), and interview with the laboratory general supervisor on August 26, 2025, at 10: 25 AM, it was determined that the laboratory failed to include external positive and negative control material each day of patient testing, when processed and reported 34 out of 63 hCG patient specimens from March 16, 2024, to July 9, 2025. The findings include: 1. The laboratory used the AimStep Combo Pregnancy Test to perform hCG testing in serum patient specimens. 2. Review of hCG quality control records and patients test worksheets on August 26, 2025, at 10:25 AM, showed that the laboratory failed to include external positive and negative control material each day of patient testing. 3. The laboratory processed and reported 34 out of 63 patient specimens from March 16, 2024, to July 9, 2025,without external controls. 4. On August 26, 2025, at 10:45 AM, the laboratory general supervisor confirmed that the laboratory did not include external positive and negative control material each day of patient testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on Mycoplasma pneumoniae and hCG quality control records, patients test worksheets review (2024 -2025), and interview with the laboratory general supervisor on August 26, 2025, at 1:00PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the analytic system requirements for Mycoplasma pneumoniae and hCG patient testing. Refer to D6093.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 and hCG quality control records, patient test worksheets review (2024 -2025), and interview with the laboratory general supervisor on August 26, 2025, at 1:00PM, it was determined that the laboratory director failed to ensure that the general supervisor monitored compliance with the analytic system requirements for Mycoplasma pneumoniae and hCG patient testing. Refer to D6144.
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 and hCG quality control records, patient test worksheets review (2024 -2025), and interview with the laboratory general supervisor on August 26, 2025, at 1:00PM, it was determined that the laboratory general supervisor failed to ensure inclusion of external positive and negative control material each day of patient testing. Refer to D5449 (A) and (B).