Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0970455	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Ceibeno	Ave Lauro Pinero 292, Ceiba, 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 Laboratorio Clinico Ceibeno on January 14, 2025. Tha laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on January 14, 2025.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (years 2023-2024) and laboratory testing personnel interview on January 14, 2025 at 9:45 am, it was determined that the laboratory director (laboratory sole personnel) failed to sign the proficiency attestation statements. The findings include: 1. Puerto Rico Proficiency testing records from years 2023 and 2024 were reviewed on January 14, 2025 at 9:40 am. 2. Review of the attestation statements form, on January 14, 2025 at 9:45 am, showed that the laboratory was instructed to print, fill, sign and retain the page for laboratory records and inspection purposes. Review of the attestation statements forms from years 2023 and 2024, showed that none of them were signed by the laboratory director. 3. On January 14, 2025 at 9:45 a.m., the laboratory director confirmed that the attestation statements from years 2023 and 2024, were never signed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on syphilis serology quality control and patient test worksheet records, manufacturer's instructions review, and laboratory director interview, on January 14, 2025 at 12:55 pm, it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 869 patient specimens were processed and reported from January 1, 2024 to January 14, 2025. The findings include: 1. The laboratory uses the ASI's reagent kit to perform patient syphilis serology test. Review of the ASI's manufacturer's instructions on January 14, 2025 at 12:55 pm, showed that the laboratory must remove and wash the needle at the end of the day. 2. On January 14, 2025 at 12:55 pm the syphilis serology quality control and patient test worksheet records were reviewed. The records showed that the laboratory did not perform the needle wash as required by the manufacturer, when they processed and reported 869 patient specimens from January 1, 2024 to January 14, 2025. 3. The laboratory director confirmed on January 14, 2025 at 1:00 pm, that the laboratory did not follow the manufacturer's instructions related to the needle wash, from January 1, 2024 to January 14, 2025.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of hematology stain quality control records and interview with the laboratory director on January 14, 2025 at 10:50 am, it was determined that the laboratory did not document the required information related to the reagent. The findings include: 1. The laboratory performs hematology staining with Wrights One Step Stain reagent. 2. On January 14, 2025 at 10:50 am, the hematology stain quality control records showed that the laboratory did not document the required following information: reagent, lot and expiration date from January 1, 2024 to December 31, 2024 when they processed and reported 2 hematology patient's staining results. 3. The laboratory director confirmed on January 14, 2025 at 10:55 am that the laboratory failed to document the reagent, lot and expiration date of the hematology stain kit that was in use from January 1, 2024 to December 31, 2024.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

	This STANDARD is not met as evidenced by: A. Based on Mycoplasma pneumoniae IgM test manufacturer's instructions, worksheet records review and laboratory director interview on January 14, 2025 at 1: 18 pm, it was determined that the laboratory failed to follow manufacturer's instructions to document the temperature and the internal control each day of patient testing. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. 2. Review of the manufacturer's instructions on January 14, 2025 at 1:17 pm showed that the laboratory must monitor and document the temperature and internal control to ensure the validity of the Mycoplasma pneumoniae IgM test performed. 3. The Mycoplasma pneumoniae IgM test worksheet records showed on January 14, 2025 at 1:18 pm, that the laboratory did not document the temperature nor the observed results of the internal procedural control with each day of patient testing when processing Mycoplasma pneumoniae IgM samples. 4. The laboratory processed and reported 595 Mycoplasma pneumoniae IgM patient samples from January 1, 2024 to January 14, 2025. 5. The laboratory director confirmed on January 14, 2025 at 1:22 pm, that the laboratory did not monitor and document the temperature nor the internal control with each day of patient testing when processing Mycoplasma pneumoniae IgM samples.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 syphilis serology, hematology stain and Mycoplasma pneumoniae quality control records review from January 1, 2024 to January 14, 2025, and interview with the laboratory director on January 14, 2025 at 1:22 pm, it was determined that the laboratory director (sole personnel) did not ensure that quality control procedures for the syphilis serology, hematology, nor the Mycoplasma pneumoniae tests were being followed. Refer to D5411, D5415 and D5479.