Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0993164	10/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Emanuel	Carr # 2, Km 30 Hm 4, Parcelas 18 C, Vega Alta, 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	A offsite revisit survey was completed on November 13, 2024 for all previous deficiencies cited on October 4, 2024. A phone call was conducted on November 14, 2024 to review the submitted PoC. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 testing records review (2024) and laboratory general supervisor interview on October 5,2024 at 9:10 A.M., it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2023 to September 2024. ((review at 9:10 A.M.) 2. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2024. (review at 9:15 A.M.) 3. The laboratory testing personnel confirmed on October 5, 2024 at 9:20 A.M that the laboratory director and testing personnel failed to sign the attestation statements since february 2024.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the review of the proficency testing program record (year 2024) and interview with the laboratory testing personnel on October 5, 2024 at 9:15 AM, it was determined that the laboratory director fail to meet the required requirements under subpart H. Refer to D2009.
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 records files review (years 2023-2024) and the laboratory testing personnel interview on October 5, 2024 at 11:20 AM, it was determined that the laboratory failed to ensure that a comprehensive mechanism is used to evaluate the competency of the testing personnel. The finding includes: 1. The laboratory testing personnel includes on medical technologist (technical consultant) . 2. The testing personnel records for medical technologist showed on October 5, 2024 at 11:20 A.M that the laboratory did not include the following requirements in his competency evaluation performed in february 2024: a. Direct observations of routine patient test performance , including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing record and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of problem solving skills.