Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0965124	04/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Avanzado Emmanuel	Carretera Pr-693, Km 7, Hm 6, Local 1-B Mahi Mahi, Dorado, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, patients specimens referral records, and laboratory testing personnel interview on April 12, 2023 at 10:00 AM, it was determined that the laboratory used supplies for the sample collection procedures that have exceeded their expiration date. The findings include: 1. The laboratory had two sample collection stations. On April 12, 2023 at 9:00 AM, it was observed in the sample collection area and in the refrigerator that the laboratory had in use EDTA sodium citrate tubes with exceeded expiration date since January 31, 2023 (Lot:2109030 exp. 1/31/2023). 2. On April 12, 2023 at 9:11 AM the referral records were requested. From February 1, 2023 to April 11, 2023, the sample referral records showed that 62 out of 62 patient specimens for D-dimer, PT and PTT tests were colleted with the expired blue top tubes (Lot 2109030). 3. On April 12, 2023 at 10:00 AM the laboratory testing personel confirmed, that the laboratory collected 62 out of 62 patient specimens for D-dimer, PT and PTT with the EDTA sodium citrate tube with lot (Lot 2109030), with an exceeded expiration date on January 31, 2023.
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: 1. Based on General Immunology (Mycoplasma pneumoniae test by Immunocard) quality control records review (years 2021-2022) and interview with the laboratory testing personel on April 12, 2023 at 12:35 PM , it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing from September 6, 2022 to December 30, 2022 when processed and reported 129 out of 173 patient's specimen. The findings include: a. General Immunology (Mycoplasma pneumoniae test) quality control records were review on April 12, 2023 at 12:08 PM, from January 1, 2021 to December 31, 2022. b. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include the external control material from September 6, 2022 to December 30, 2022 when processed and reportes sample patient specimens. c. The laboratory testing personel confirmed on April 12, 2023 at 12:35 PM, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test from September 6, 2022 to December 30, 2022 when 129 out of 173 patient's were processed and reported. 2. Based on Rapid Reagin Plasma (RPR) quality control records review (years 2021-2022) and interview with the laboratory testing personel on April 12, 2023 at 11:30 AM; it was determined that the laboratory did not include the reactive and non-reactive control material on July 28, 2022 when four (4) out Four (4) patient's specimen was processed and reported for RPR. The findings include: a. The RPR quality control records were reviewed on April 12, 2023 at 11:10 AM, from January 1, 2021 to December 31, 2022.The RPR quality control record showed that the laboratory did not include any control material on July 28, 2022 when the laboratory processed and reported four (4) out Four (4) patient's specimen. c. The laboratory testing personel confirmed on April 12, 2023 at 11:30 A.M, that the laboratory failed to include a reactive and non-reactive control material on July 28, 2022 when the laboratory processed and reported four (4) out Four (4) patient's specimen.
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 quality control records review, direct observation and laboratory testing personel interview on April 12, 2023 at 12:35 PM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5417, D5449 .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on Mycoplasma testing records and testing personel interview on April 12, 2023 at 12:35 PM, it was determined that the technical consultant did not ensure that the quality control that was established were followed, for the mycoplasma test. Based on Rapid Reagin Plasma (RPR) testing records and testing personel interview on April 12, 2023 at 11:30 AM, it was determined that the technical consultant did no ensure that the quality control that was established were followed. Refer to D 5449.