Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2007082	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Tu Salud	Road 417 Km 4 Hm 2 Barrio Mamey, Aguada, 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 TU SALUD on July 24, 2024. The 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 July 24, 2024.
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 Program testing records review (years 2023 and 2024) and laboratory director interview on July 24, 2024 at 10:38 AM, it was determined that the laboratory director failed to sign the proficiency attestation statements. The findings include: 1. Puerto Rico Proficiency testing records from years 2023 and 2024 were reviewed on July 24, 2024 at 10:38 A.M. 2. On July 24, 2024 at 10:40A.M. the attestation statements instructed the laboratory to print, fill, sing 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 director nor the individual who tested the samples. 3. The laboratory director confirmed on July 24, 2024 at 10:45 A.M., that the laboratory director failed to sign the proficiency attestation statements.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when

	applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on syphilis serology test manufacturer's instructions (AIM) , syphilis serology quality control records, patient's reports worksheets review (years 2023-2024) and laboratory director interview on July 24, 2024 at 10:35AM, it was determined that the laboratory failed to follow the manufacturer's instructions when reported and performed 148 out of 148 syphilis serology patient's samples by Aim Rapid plasma reagin (RPR) method in 63 out of 63 days since March 11, 2024. The findings include: 1. The laboratory begin to use a new method for Rapid plasma reagin (RPR-AIM test) on March 11, 2024. (Reviewed on July 24, 2024 at 9:33 AM.) 2. The manufacturer's instructions establishes that three levels of control material (non-reactive, minimal to moderate and reactive) must be included each day of testing. (Reviewed on July 24, 2024 at 9:33 AM. 3. From March 11, 2024 to July 23, 2024 (31 days), the syphilis serology quality control records and the patient's reports worksheet showed that the laboratory did not include the minimal to moderate control material when it processed and reported 148 patient's specimens for syphilis serology by Aim RPR method. (Reviewed on July 24, 2024 at 9:45AM). 4. The laboratory director stated on July 24, 2024 at 9:55AM that the laboratory did not include the three levels of control material when it processed and reported patients specimens for syphilis serology by Aim RPR method those days.
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 proficiency program records (year 2023-2024) and interview with the laboratory director on July 24, 2024 at 10:45 A.M., it was determined that the laboratory director fail to meet the required requirements under subpart H. Refer to D2009.
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 syphilis serology quality control records review from March 11, 2024 to July 23, 2024, and interview with the laboratory director on July 24, 2024 at 11:00A.. M., it was determined that the laboratory director (sole personnel) did not establish quality control procedures for the syphilis serology tests when changed RPR method on March 11, 2024. Refer to D5405.