Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1009496	01/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Toledo	Carr Pr-2 Km 78 Hm 6 Ave Miramar 1079, Arecibo, 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
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphilis serology quality control records, patients reports worksheets review (years 2021-2022) and laboratory technical consultant interview at 10:00 AM on January 30, 2023, it was determined that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test by ASI RPR Method for positive and negative reactivity prior to placed it in routine use when reported and performed 392 out of 392 syphilis serology patients samples. The findings include: 1. The laboratory syphilis serology quality control records were review from May 2021 to January 30, 2023. (reviewed on 1/30/2023 at 10:00 a.m.) 2. The patient reports worksheets (2021-2022) showed on January 30, 2023 at 10:10 a.m., that the laboratory received the following reagent kit for RPR Method and no evaluation of their reactivity was performed: Test Lot a. RPR CAOM13RB exp. date: 11/2022 opened day : 5/18/2021 b. RPR lot: 2B07R6 exp. date: 1/30/2023 opened day : 5/30/22 3. The laboratory used the lot CAOM13RB from 5/18/2021 to 10/20/2021 and reported and processed one hundred ninety (190) RPR (Rapid plasma reagin) patient's samples. (reviewed on 1/30/2023 at 10:13 a.m.) 4. The laboratory used the lot 2B07R6 from 5/30/2022 to 12/8/2022 and reported and processed two hundred two (202) RPR (Rapid plasma reagin) patient's samples. (reviewed on 1/30/2023 at 10:17 a.m.) 5. The laboratory technical

	consultant confirmed on January 30, 2023 at 10:30 a.m. that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use.
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 (2021-2022) and laboratory director interview on January 30, 2023 at 11:00 a.m., it was determined that laboratory director did not ensure that the RPR analytical requirements were monitored by the technical consultant. Refer to D5471. (The laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test by ASI RPR Method for positive and negative reactivity prior to placed it in routine use).
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 Syphilis serology quality control records review (2021-2022) and laboratory technical consultant interview on January 30, 2023 at 10:45 a.m., it was determined that the technical consultant did not ensure that the laboratory evaluate the new lot of Rapid Plasma reagin (RPR) test by ASI RPR Method for positive and negative reactivity prior to placed it in routine use. Refer to D5471.