Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1046214	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Olympic Plaza	Extension Centro Comercial, Caribbean Shopping, Las Piedras, 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
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphilis serology testing records(year 2023) review and laboratory director interview on January 3, 2024 at 10:27 AM, it was determined that the laboratory failed to include at least once a day, a negative control material and the control material with tittered reactivity when two (2) out of two (2) patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method from October 24, 2023 to December 4, 2023. The findings include: 1. The laboratory processed and reported the RPR quantitative tests by ASI method. 2. On January 3, 2024 at 10:19 AM, the syphilis serology testing records showed that the laboratory did not include at least once a day, the negative control material and the control material with tittered reactivity. 3. The laboratory director confirmed on January 3, 2024 at 10:27 AM, that the laboratory did not include the negative control material and the control material with tittered reactivity when it performed the quantitative RPR test. Two (2) out of two (2) patients specimens were tested for RPR quantitative tests by ASI method on the following days: October 24, 2023 and December 4, 2023.
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 worksheet records review (year 2023), and interview with the laboratory director on January 3, 2024 at 11:10 AM, it was determined that the laboratory director did not ensure that quality control procedures for syphilis serology quantitative method being followed. Refer to D5451.