Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0689290	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Munoz Rivera	Esmeralda 51 Munoz Rivera, Guaynabo, 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 (years 2022 and 2023) review and laboratory supervisor interview on August 16, 2023 at 11:43 AM, it was determined that the laboratory failed to include at least once a day, a negative control material besides a control material with tittered reactivity when 3 out 3 patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method from April 12, 2023 to May 16, 2023. The findings include: 1. The laboratory processed and reported the RPR quantitative tests by ASI method. 2. On August 16, 2023 at 11:30 AM, the syphilis serology testing records was reviewed and showed that the laboratory did not include at least once a day, the negative control material besides the control material with tittered reactivity when 3 out 3 patients specimens were tested for RPR quantitative tests by ASI method from April 12, 2023 to May 16, 2023. 3. The laboratory supervisor confirmed on August 16, 2023 at 11:43 AM, that the laboratory did not include the negative control material and the control material tittered reactivity when it performed the quantitative RPR test. She stated that the laboratory includes this control material when it processing the qualitative RPR test.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Syphilis Serology test quality control records (year 2022 and 2023) review and interview with the laboratory supervisor on August 16, 2023 at 11:43 AM, it was determined that the laboratory director failed to ensure that the laboratory maintain the quality control procedures for the Rapid Reagin Plasma test (RPR) quantitative test. Refer to D5451.