

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0675423	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Laboratorio Clinico Rosario	Street Address, City, State Calle C Blq A-24 Jardines De Carolina, Carolina, 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 ROSARIO on July 16, 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 16, 2024.
D5451	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology testing records (year 2023 and 2024) review and laboratory supervisor interview on July 16, 2024 at 11:37 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 one (1) out of one (1) patient specimen were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method on May 28, 2024. The findings include: 1. The laboratory processed and reported the RPR quantitative tests by ASI method. 2. On July 16, 2024 at 11:19 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 supervisor confirmed on July 16, 2024 at 11:37 AM, that the laboratory did not include the negative control material and the control material</p>

with tittered reactivity when it performed the quantitative RPR test. One (1) out of one (1) patient specimen were tested for RPR quantitative tests by ASI method on May 28, 2024.

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 records review (year 2023 and 2024) and interview with the laboratory supervisor on July 16, 2024 at 11:37 AM; it was determined that the laboratory director failed to ensure that the quality control for tittered syphilis serology test were followed. Refer to D5451