

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658291	(X3) Date Survey Completed 07/03/2025
Name of Provider or Supplier Lab Clin Borinquen - Las Lomas	Street Address, City, State Carr 21 U-3 Urb Las Lomas, Rio 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Borinquen - Las Lomas on July 3, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on July 3, 2025.
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p> <p>This STANDARD is not met as evidenced by: Based on urinalysis quality control records review (years 2024-2025) and laboratory supervisor interview on July 3, 2025 at 11:02 AM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials (normal and abnormal controls), when the laboratory processed and reported 951 patient urinalysis samples from January 1, 2025 to January 31, 2025. The findings include: 1. The laboratory performs urinalysis tests with the iChem VELOCITY instrument and uses IRISpec urine control material. 2. The urinalysis quality control records reviewed (years 2024-2025) on July 3, 2025 at 11:02 AM, from January 1, 2025 to January 31, 2025, showed that there was no evaluation of the manufacturer's stated values for the normal and abnormal kit control material lot number 614-24 prior to placing them in</p>

routine use on January 31, 2025. 3. The laboratory director stated on July 3, 2025 at 11:02 AM, that no evaluations of the stated lot of control materials were performed prior to placing them in routine use. 4. The laboratory director confirmed on July 3, 2025 at 11:10 AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for urinalysis tests performed by the iChem VELOCITY instrument, when they processed and reported 951 patient samples from January 1, 2025 to January 31, 2025.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment 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 urinalysis quality control records review (years 2024-2025), it was determined that the laboratory director did not ensure that quality control procedures related to urinalysis quality control procedures were performed as established by the urinalysis quality control requirements. Refer to D5469.