Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0715749	10/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Punta Las Marias	Loiza Street #2426, Santurce, 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 the Laboratorio Clnico Punta Las Marias on October 24, 2025. 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 October 24, 2025.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(1) 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. This STANDARD is not met as evidenced by: Based on the review of human chorionic gonadotropin (hCG) test quality control records (year 2024-2025) and an interview with the laboratory general supervisor on October 24, 2025, at 10:20 AM, it was determined that the laboratory failed to evaluate the new lot of hCG test kits for positive and negative reactivity prior to placing the lot in routine use on November 13, 2024. The findings include: 1. The laboratory performed hCG testing using the Instant-View Pregnancy and FaStep S10 HCG Serum/Urine Combo Cassette method. 2. The hCG quality control test records were reviewed from January 4, 2024, to October 22, 2025, and showed that the laboratory did not evaluate the new lot of hCG test kits for positive and negative reactivity prior to use in patient testing. A. Method: Instant-View Pregnancy Combo Lot Number: 088160 Expiration date: May 31, 2026 Date opened: November 13, 2024 The laboratory processed and reported 47 out of 47 patient specimens from November 13, 2024, to April 1, 2025. B. Method: Instant-View Pregnancy Lot

	Number: 088710 Expiration date: July 31, 2026 Date opened: April 2, 2025 The laboratory processed and reported 34 out of 34 patient specimens from April 2, 2025, to June 26, 2025. C. Method: FaStep S10 HCG Serum/Urine Combo Lot Number. F2406019 Expiration date: May 2026 Date opened: June 27, 2025 The laboratory processed and reported 40 out of 40 patient specimens from June 27, 2025, to October 22, 2025. 3. The laboratory processed and reported 121 out of 121 hCG patient specimens from November 13, 2024, to October 22 ,2025. 4. The laboratory general supervisor confirmed on October 24, 2025, at 11:50 AM, that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use.
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 the review of hCG quality control records (year 2024-2025) and an interview with the laboratory general supervisor on October 24, 2025, at 12:00 PM, it was determined that the laboratory director failed to ensure that the general supervisor monitored compliance with analytic system requirements for new lots of hCG test kits for positive and negative reactivity prior to placing them in routine use. Refer to D6144.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on the review of hCG quality control records review and an interview with the laboratory general supervisor on October 24, 2025, at 12:00 PM, it was determined that the laboratory general supervisor failed to verify the new lots of hCG test kits for positive and negative reactivity prior to placing them in routine use. Refer to D5471.