Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0663215	02/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Laracuente	Calle Mendez Vigo #291, Dorado, 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	An unannounced CLIA Recertification survey was conducted at the Laboratorio Clnico Laracuente on February 7, 2025 by the Puerto Rico State Agency. 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 on February 7, 2025.
D2071	SYPHILIS SEROLOGY CFR(s): 493.835(c) (c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing (PRPT) event scores (years 2023-2024), CASPER Report 0155D, PRPT (year 2024) schedule and laboratory director interview on February 7, 2025, at 9:00 A.M., it was determined that the laboratory failed to report the syphilis serology proficiency testing results within the time frame established by the program. The findings include: 1. The PRPT and CASPER Report were reviewed on February 7, 2025, at 9:00 A.M., from February 2023 to December 2024. 2. The PRPT schedule for year 2024 showed that the deadline of the first testing event for Diagnostic Immunology scores was April 19, 2024. (Reviewed on February 7, 2025, at 9:05 A.M.) 3. Review of the PRPT scores showed that the laboratory obtained a 0% score in the first testing event, year 2024, for syphilis serology tests. (Reviewed on February 7, 2025, at 9:10 A.M.) 4. The laboratory director confirmed on February 7, 2025, at 10:30 A.M., that the laboratory failed to report the syphilis serology proficiency testing results of the first testing event within the time frame established by the PRPT.
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 human chorionic gonadotropin (hCG) test quality control records review (year 2024), hCG test new lot reactivity worksheet records and laboratory director interview on February 7, 2025 at 1:00 P.M, it was determined that the laboratory did not evaluate the new lots of hCG test for positive and negative reactivity prior to placing it in routine use, when 35 out of 35 patient specimens were processed and reported from April 29, 2024 to December 30, 2024. The findings include: 1. On February 7, 2025, at 1:00 P. M, the laboratory director stated that the laboratory performed qualitative hCG tests with the Instant-View Combo Cassettes. 2. The hCG quality control test records and hCG test new lot reactivity worksheet records were reviewed from January 2, 2024, to December 30, 2024, and showed that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use: Lot Number: 085391, Expiration date :7/31/25, Date opened: 4/29/24. 3. The laboratory performed and reported 35 out of 35 hCG patient samples. (Reviewed on February 7, 2025, at 1:07 P.M.) 4. The laboratory director confirmed on February 7, 2025, at 1:15 P.M., that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing scores (years 2023-2024) and CASPER Report and laboratory director interview on February 7, 2025, at 10:40 A.M, it was determined that the laboratory director failed to report the Diagnostic Immunology proficiency testing results within the time frame established by the program, getting a score of 0% in the first event for syphilis serology. Refer to D2071.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 endocrinology quality control (hCG test) record review and laboratory

	director interview on February 7, 2025, at 1:30 P.M., it was determined that the laboratory director failed to ensure that the laboratory evaluated the new lot of hCG test for positive and negative reactivity prior to placing it in routine use. Refer to D5471.