Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0977871	02/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Obymar	Carr 420 Km 04 Barrio Voladoras, Moca, 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 Obymar on February 5, 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 5, 2025.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of syphilis serology quality control records, syphilis serology patient test worksheet (years 2023-2024), Aim Rapid Plasma Reagin (RPR) test manufacturer's instructions and laboratory director interview, on February 5, 2025, at 11:00 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions regarding needle washing after each shift for the syphilis serology testing, when 218 out of 218 patient specimens were tested from January 3, 2024 to December 24, 2024. The findings include: 1. The laboratory uses the Aim RPR test to perform patient syphilis serology tests. Review of the Aim RPR manufacturer's instructions on February 5, 2025, at 11:00 A.M., established that the needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. 2. On February 5, 2025, at 11:05 A.M., the syphilis serology quality control and patient test worksheet records were reviewed. The records showed that the laboratory did not perform nor document the needle wash as required by the manufacturer, when they processed and reported 218 out of 218 RPR patient specimens from January 3, 2024, to December 24, 2024. 3. The laboratory director confirmed during interview on

	February 5, 2025, at 11:20 A.M., that the laboratory did not follow the manufacturer's instructions related to the needle wash.
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 syphilis serology quality control and patient test worksheet (RPR) record review and laboratory director interview on February 5, 2025, at 1:30 P.M., it was determined that the laboratory director failed to ensure that the laboratory general supervisor followed the manufacturer's instructions related to the needle wash after each shift. 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 syphilis serology quality control and patient test worksheet (RPR) record review and laboratory director interview on February 5, 2025, at 1:30 P.M., it was determined that the laboratory general supervisor did not assure that the testing personnel followed the manufacturer's instructions regarding needle washing after each shift for the syphilis serology testing. Refer to D5411.