Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0926346	10/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Lab Servi Lab Reference	Fernandez Garcia St 109, Luquillo, 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 Servi-Lab on October 3, 2024 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on October 3, 2024, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1210 Routine Chemistry 42 CFR 493.1441 Laboratory Director, High Complexity Testing
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on routine chemistry daily maintenance records review (years 2023-2024), observation in the phlebotomy area (Serum Gel Red Cap Vacuette tubes for routine chemistry test sample) and interview with the laboratory testing personnel (TP#3) on October 3, 2024 at 12:30 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry. Refer to D5411(B) and D5417. The findings include: 1. The routine chemistry daily maintenance records review showed that the laboratory did not follow the cuvette temperature range required. Refer to D5411 (B) 2. The laboratory used sample collection tubes (direct observation in the phlebotomy area), with exceeded expiration dates. Refer to D5417.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: A. Based on syphilis serology quality control, syphilis serology patient test worksheet records (years 2023-2024), ASI Rapid Plasma Reagin (RPR) manufacturer's instructions review and laboratory testing personnel interview, on October 3, 2024, at 11:20 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions regarding to the needle wash after each shift for the syphilis serology tests, when 1439 out of 1439 patient specimens were tested from January 2, 2024 to October 2, 2024. The findings include: 1. The laboratory uses the ASI RPR card test to perform patient syphilis serology tests. Review of the ASI RPR manufacturer's instructions on October 3, 2024, at 11:20 A.M., established that the needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. 2. On October 3, 2024, at 11:30 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 1439 out of 1439 RPR patient specimens from January 2, 2024, to October 2, 2024. 3. The laboratory testing personnel confirmed during interview on October 3, 2024, at 11:45 A.M., that the laboratory did not follow the manufacturer's instructions related to the needle wash. B. Based on daily maintenance records review (years 2023-2024), Dimension EXL 200 Integrated Chemistry System manufacturer's instructions review and laboratory testing personnel interview, on October 3, 2024, at 10:00 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions regarding to the established temperature range for cuvette on 97 out of 190 days of year 2024. The records showed that the laboratory processed and reported routine chemistry patient's specimen below the established temperature range. The findings include: 1. The laboratory uses Dimension EXL200 Integrated Chemistry System to perform routine chemistry tests. (Reviewed on October 3,2024 at 10:00 A.M.) 2. On October 3,2024 at 10:05 A.M., the Dimension EXL200 Integrated Chemistry System manufacturer's instructions were reviewed. The manufacturers require a cuvette temperature range of 36.8C to 37.2C for patient samples processing. 3. On October 3,2024 at 10:10 A.M., the daily maintenance records review showed that the laboratory did not follow the manufacturer's instructions when they processed and reported 2,018 patient samples, below the established cuvette temperature range on 97 out of 190 days of year 2024. 4. The laboratory testing personnel confirmed during interview on October 3,2024, at 10:15 A.M., that the laboratory did not follow the manufacturer's instructions regarding to cuvette temperature requirement on 97 out of 190 days of year 2024.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation in the phlebotomy area of the laboratory, chemistry patient census review (years 2024), and interview with the testing personnel on

	October 3, 2024, at 12:09 P.M., it was determined that the laboratory used sample collection tubes with exceeded expiration dates. From June 9, 2024, to October 3, 2024, the laboratory collected, processed, and reported 693 out of 693 routine chemistry patient specimens with expired collection tubes. The findings include: 1. On October 3, 2024, at 12:09 P.M., the laboratory phlebotomy area was observed. The Greiner Serum Gel Red Cap Vacuette tubes, lot number B221237U, with expiration date 2024/06/08 were found. The laboratory testing personnel established during interview, that the Greiner Serum Gel Red Cap Vacuette tubes were used to collect routine chemistry patient's specimen. 2. The chemistry patient census review on October 3, 2024, at 12:15 P.M., showed that laboratory collected, processed, and reported 693 out of 693 patient tests with sample collection tubes with exceeded expiration date from June 9,2024 to October 2,2024. 3. The laboratory testing personnel confirmed during interview, on October 3,2024, at 12:20 P.M., that the laboratory used sample collection tubes (Serum Gel Red Cap Vacuette tubes for routine chemistry test sample) that exceeded their expiration date from June 10,2024 to October 2,2024.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on routine chemistry daily maintenance records review (years 2023-2024), observation in the phlebotomy area (Serum Gel Red Cap Vacuette tubes for routine chemistry test sample) and interview with the laboratory testing personnel (TP#3) on October 3, 2024, at 12:30 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the analytic system requirements for routine chemistry. Refer to D6093.
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 routine chemistry daily maintenance records review, syphilis serology quality control and patient test worksheet (RPR), direct observation in the phlebotomy area and laboratory testing personnel interview on October 3, 2024, at 12:30 P.M., it was determined that the laboratory director did not assure that the manufacturer's instructions were followed in the laboratory. Refer to: D5411 and D5417. The findings include: 1. The syphilis serology quality control and patient test worksheet (RPR) records showed that the laboratory did not perform nor document the needle wash as required by the manufacturer. Refer to D5411 (A) 2. The routine chemistry daily maintenance records review showed that the laboratory did not follow the

	cuvette temperature range required. Refer to D5411 (B) 3. The laboratory used sample collection tubes (direct observation in the phlebotomy area), with exceeded expiration dates. Refer to D5417.
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 routine chemistry daily maintenance records review, syphilis serology quality control and patient test worksheet (RPR), direct observation in the phlebotomy area and laboratory testing personnel interview on October 3, 2024, at 12:30 P.M., it was determined that the general supervisor (GS#4) did not assure that the manufacturer's instructions were followed by the testing personnel regarding to: cuvette temperature range for chemistry system, needle wash after each shift for the syphilis serology (RPR) tests and the used of sample collection tubes with exceeded expiration. Refer to: D5411 and 5417.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on routine chemistry daily maintenance records review, syphilis serology quality control and patient test worksheet (RPR), observation in the phlebotomy area (Serum Gel Red Cap Vacuette tubes for routine chemistry test sample) and laboratory testing personnel (TP#3) interview on October 3, 2024, at 12:30 P.M., it was determined that the TP#3 did not follow the manufacturer's instructions regarding for the syphilis serology (RPR) tests and routine chemistry tests. Refer to: D5411 and 5417.