Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0965500	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Sinai	Carr 119 Km 9 Hm 2 Bo Camuy Arriba, Camuy, 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 Sinai on December 5, 2024 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: D5411: Test Systems, Equipment, Instruments, Reagent CFR(s): 493.1252(a) D5445: Control Procedures CFR(s): 493.1256(d)(1)(2)(g)
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 and patient test worksheet records (years 2023-2024), ASI Rapid Plasma Reagin (RPR) manufacturer's instructions review, and laboratory director interview, on December 5, 2024, at 10:45 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 1043 out of 1043 patient specimens were tested from January 2, 2023 to December 4, 2024. The findings include: 1. The laboratory uses the ASI's RPR card test to perform patient syphilis serology tests. Review of the ASI's RPR manufacturer's instructions on December 5, 2024 at 10:45 A.M., established that the needle must be cleaned at the end of each shift, using a syringe or pipet. 2. On December 5, 2024, at 10:55 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 cleaning as required by the manufacturer, when processed and reported 1043 out of 1043 RPR patient specimens from January 2, 2023 December 4, 2024. 3. The laboratory director confirmed during interview on December 5, 2024, at 11:05 A.M., that the laboratory did not follow the

	manufacturer's instructions regarding the needle cleaning. B. Based on syphilis serology quality control and patient test worksheet records (years 2023-2024), ASI Rapid Plasma Reagin (RPR) manufacturer's instructions review, and laboratory director interview, on December 5, 2024, at 10:45 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 37 out of 37 patient specimens were tested from October 24, 2024 and December 4, 2024. The findings include: 1. The laboratory uses the ASI's RPR card test to perform patient syphilis serology tests. Review of the ASI's RPR manufacturer's instructions on December 5, 2024 at 10:45 A.M., established that the carbon antigen may be stored for up to one month in the dropping bottle at 2-8C. 2. On December 5, at 10:50 A.M., the syphilis serology quality control and patient test worksheet records showed that the carbon antigen lot number CA3J16RY, with expiration date in August 2025, was dispensed in the dropping bottle on September 23, 2024. It was observed on December 5,2024, that the laboratory continue to use the mentioned lot number after October 23, 2024. The laboratory had in use the same reagent until December 4, 2024. 3. The laboratory processed and reported 37 out of 37 RPR patient specimens from October 24, 2024 to December 4, 2024. (Reviewed on December 5,2024 at 10:58AM) 4. The laboratory director confirmed during the interview on December 5, 2024 at 11:15 A.M., that the laboratory did not follow the manufacturer's instructions regarding the carbon antigen after the month.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the microscopy urinalysis quality control records (years 2023-2024), written procedure for quality control of urinalysis, and laboratory director interview on December 5,2024 at 11:30 A.M.; it was determined that the laboratory failed to include two levels of control material, when processed 4,366 out of 4,366 patient specimens for urinalysis sediment between January 2,2023 and December 4,2024. The findings include: 1. The written procedure for urinalysis quality control stated that, in each shift, normal and abnormal commercial controls must be used to evaluate the accuracy and precision of the microscopic examination. Results will be documented and initiated. (Reviewed on December 5,2024 at 11:40 A.M.) 2. On December 5,2024 at 11:30 A.M., the microscopy urinalysis quality control records from January 2,2023 to December 4, 2024, showed that the laboratory failed to include both, positive and negative control materials, at least each day of patient testing. 3. During interview with the laboratory director confirmed on December 5,2024 at 11:45 A.M., that the laboratory did not include any control material for microscopy urinalysis. 4. The laboratory processed and reported 4,366 out of 4,366 patient specimens for urinalysis sediment between January 2,2023 and December 4,2024. (Reviewed on December 5,2024 at 12:10 P.M.)

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on syphilis serology quality control and patient test worksheet (RPR), urinalysis quality control record review and laboratory director (sole personnel) interview on December 5, 2024, at 1:30 P.M., it was determined that the laboratory director did not assure that the manufacturer's instructions and written procedure were followed in the laboratory. Refer to: D5411 and 5445.