Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2030981	04/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Santa Olaya	Barrio Santa Olaya Carretera 829 Km 6 Hm 2, Bayamon, 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
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on syphilis serology quality control records (year 2023-2024), syphilis Rapid Plasma Reagin (RPR) written procedure, ASI RPR manufacturer's instructions review and laboratory director interview on April 3,2024 at 3:30 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory did not wash the dispensing needle after each day of use. (Refer to D5411) 2. The laboratory used an expired RPR antigen reagent. (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: 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 director interview, on April 3, 2024, at 12:40 P.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 205 out of 205 patient specimens were tested from January 4, 2023, to March 25, 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 April 3 , 2024 at 12:40 P.M., established that the needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. 2. On April 3, 2024, at 12: 45 P.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 205 out of 205 RPR patient specimens from January 4, 2023, to March 25, 2024. 3. The laboratory director confirmed during interview on April 3,2024 at 12:50 P.M., that the laboratory did not follow the manufacturer's instructions related to the needle wash.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae testing record review (years 2023-2024), ImmunoCard Mycoplasma manufacturer's instructions, ImmunoCard Mycoplasma written procedure review and laboratory director interview on April 3, 2024, at 12:00 P.M., it was determined that the laboratory failed to follow the manufacturer's instruction regarding to the established temperature range for Mycoplasma pneumoniae when 223 out of 223 patient's specimens were processed and reported for Mycoplasma pneumoniae from January 3, 2023, to March 26,2024. The findings include: 1. The laboratory uses the ImmunoCard Mycoplasma Test Kit to perform the Mycoplasma pneumoniae qualitative tests. (Reviewed on April 3,2024 at 12:00 P.M.) 2. On April 3,2024 at 12:02 P.M., the ImmunoCard Mycoplasma manufacturer's instructions and written procedure were reviewed. The manufacturer's instructions and the written procedure established to perform the Mycoplasma pneumoniae test procedures between 22C to 25 range temperature. 3. On April 3,2024 at 12:10 P.M., the Mycoplasma pneumoniae testing records review showing that the laboratory did not monitor nor document the room temperature when it processed and reported 223 out of 223 patient's specimens for Mycoplasma pneumoniae test from January 3,2023 to March 26,2024. 4. The laboratory director confirmed during interview on April 3,2024, at 12:27 P.M., that the laboratory did not monitor nor document the room temperature when it processed the patient's specimens for Mycoplasma pneumoniae test.
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:
A. Based on direct observation in the phlebotomy area of the laboratory, chemistry patient census review (years 2023-2024), and interview with the general supervisor on April 3, 2024, at 8:45 A.M., it was determined that the laboratory used sample collection tubes with exceeded expiration dates. From December 1, 2023, to April 2, 2024, the laboratory collected, processed, and reported 1,411 out of 1,756 routine chemistry patient specimens with expired collection tubes. The findings include: 1. On April 3, 2024, at 8:45 A.M., the laboratory phlebotomy area was observed. The Improvacuter Gel & Clot Activator dark yellow top tubes, lot number A12012, with expiration date 2023-11 were found. The general supervisor established during interview that used the Improvacuter Gel & Clot Activator dark yellow for routine chemistry patient's specimens. 2 The chemistry patient census review on April 3, 2024, at 8:55A.M., showed that laboratory collected, processed, and reported 1,411 out of 1,756 patient's tests with sample collection tubes with exceeded expiration date from December 1,2023 to April 2,2024. 3.The general supervisor confirmed during interview, on April 3,2024, at 9:05 A.M., that the laboratory used sample collection tubes (Gel & Clot Activator for routine chemistry test sample) that exceeded their expiration date from December 1,2023 to April 2,2024. B. Based on direct observation of the hematology quality control material, Mindray hematology control inserts, hematology patient census review and laboratory director interview on April 3, 2024, at 11:15A.M., it was determined that the laboratory used the Complete Blood Count (CBC) controls materials with exceeded stability date. The laboratory processed and reported 51 out of 51 CBC patient's specimens from March 26,2024 to April 2,2024. The findings include: 1. The laboratory used the Mindray BC-5390 Auto Hematology Analyzer for patient's specimens. (Reviewed on April 3,2024 at 11: 15 A.M.) 2. On April 3,2024 at 11:25 A.M., the Mindray BC-5D Hematology control insert was revised. The insert stated that: "opened tubes/vials were stable for 14 days" since opened. 3. On April 3,2024 at 11:36 A.M., it was observed that the laboratory opened three hematology control material vials (Mindray BC-5D hematology control lot: BC-2403 BN, BC-2403 BH and BC-2403 BL) on March 11,2024. 4. The hematology patient census showed that the laboratory processed and reported 51 out of 51 CBC patient's specimens from March 26,2024 to April 2,2024, with exceeded stability date. (Reviewed on April 3,2024 at 11:40 A.M.) 5. On April 3,2024 at 11:45 A.M., the laboratory director confirmed during interview, that the laboratory used those controls material with exceeded stability date from March 26,2024 to April 2,2024. C. Based on syphilis serology quality control records (years 2023-2024), ASI Rapid Plasma Reagin (RPR) manufacturer's instructions review and laboratory director interview, on April 3, 2024, at 12:55 P.M., it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, regarding antigen reagent, when 33 out of 33 RPR's patient specimens were tested between January 13, 2024, and April 2, 2024. The findings include: 1. The laboratory uses the ASI RPR Test Kit to perform patient syphilis serology tests. (Reviewed on April 3,2024 at 12:55 P.M.) 2. Review of the ASI RPR manufacturer's instructions on April 3 ,2024 at 1:100 P.M., establish that the carbon antigen may be stored for up to one month in the dropping bottle at 2C to 8C range temperature. 3. On April 3, 2024, at 1:15 P.M., the syphilis serology quality control records were reviewed and showed that the antigen lot number CA3E262, with expiration date in May 2025, was opened and dispensed in the dropping bottle on December 13, 2023. 4. The laboratory continue to use the antigen lot number CA3E262, after the new expiration date of January 12,2024. (Reviewed on April 3,2024 at 1:20 P.M.) 5. From

	January 13, 2024, to April 2, 2024, the laboratory used an expired reagent to process and report 33 out of 33 RPR's patient specimens. (Reviewed on April 3,2024 at 1:27 P. M) 6. The laboratory director confirmed during the interview on April 3, 2024, at 1:39 p.m., that the laboratory continued to use the antigen lot #CA3E262 after the expiration date.
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 quality control records review, and laboratory director interview on April 3, 2024, at 3:15 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. 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 general immunology (Mycoplasma pneumoniae), syphilis serology (RPR), hematology quality control records review, and laboratory director interview on April 3, 2024, at 3:30 P.M., it was determined that the laboratory did not assure that the quality control procedures were followed for the mentioned analytes. Refer to: D5411, D5413 and 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 quality control records review, and laboratory director interview on April 3,2024 at 3:45 P.M, it was determined that the general supervisor did not follow the manufacturer's instructions for general immunology (Mycoplasma pneumoniae), syphilis serology (RPR) and hematology control materials. Refer to D D5411, D5413 and D5417. .