Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0676483	09/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Central De Toa Alta	Calle Antonio Lopez # 32, Toa Alta, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2021-2022) and laboratory director interview on September 8, 2022 , it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2021 to July 2022. (review at 9:50 a.m.) 2. The review of records showed that the laboratory director and laboratory testing personnel did not sign the attestation statements of the Proficiency testing records from February 2021 to July 2022. (review at 9:55 a.m.) 3. The laboratory director confirmed on September 8, 2022 that the laboratory director and testing personnel failed to sign the attestation statements in 2021-2022. (review at 9:57a. m.)
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such

	timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on lack of Puerto Rico Proficiency Testing records (PT) , Quality Assessment records QA) , syphilis serology quality control records and laboratory director interview at 11:30 a.m. on September 8, 2022, it was determined that the laboratory failed to keep quality control records, PT records and QA records. Refer D3031, D3037 and D3039.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of syphilis serology quality control records (year 2021-2022) and laboratory director interview on September 8, 20222., it was determined that the laboratory failed to retain the syphilis serology quality control records. The findings include: 1. The laboratory used the Rapid plasma reagin (RPR) method to performed syphilis serology test. (review on September 8, 2022 at 9:00 a.m.) 2. The laboratory did not have available the syphilis serology quality control records from February 2021- to September 2022. (review on September 8, 2022 at 9:20 a.m.) 3. The laboratory processed and reported 910 syphilis serology patient samples in 2021 and 666 syphilis serology patient samples in 2022. (review on September 8, 2022 at 9:25 a.m.) 4. The laboratory director confirmed on September 8, 2022 at 11:00 A.M. , that the laboratory did not have available the syphilis serology quality control tests from February 2021-September 2022.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing records (year 2021-2022) and laboratory director interview on September 8, 2022, it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed since February 2021. (reviewed on September 8, 2022 at 9:50 a.m.) 2. The laboratory did not have available the proficiency testing records documentation of syphilis serology tests from the following testing events: third testing event 2021 first and second testing event of 2022. (reviewed on September 8, 2022 at 10:00 a.m.) 3. The laboratory director confirmed on September 8, 2022, at 11:30 A.M. , that the laboratory did not have available the Proficiency Testing records since the third testing event 2021, first and second testing event of 2022.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)

	Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records and laboratory director interview on September 8, 2022, it was found that the laboratory did not retain nor perform the evaluations of the Quality Assessment Program in order to monitor and evaluate the laboratory activities (pre-analytic, analytic and post-analytic systems) since year 2021. The findings include: 1. The laboratory did not have any document related to the QA program since year 2021. (reviewed on September 8, 2021 at 10:10 a.m.) 2. The laboratory director stated on September 8, 2022, at 11:25 PM, that the laboratory did not have available the Quality Assessment documentation in the laboratory since January 2021.
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 lack of syphilis serology testing record (year 2021-2022) and laboratory director interview on September 8, 2022 at 11:30 a.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 failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by Aim RPR method. (refer to D5405) 2. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions.(refer to D5411) 3. The laboratory performed syphilis serology (Rapid plasma reagin) patient's test with control material and reagent that exceeded the expiration date. (refer to D5417) 4. The laboratory failed to follow written instructions for the preventive maintenance of the Centrifuge and rotator instrument. refer to D5429)
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records , QA written procedures review (year 2021-2022) and laboratory director interview on September 8, 2022 at 11:45 a. m., it was determined that laboratory failed to monitor and evaluate the following general laboratory systems requirements: patient confidentiality, specimen identification and integrity, compliant investigation, communications and personnel competency.

D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment procedure manual review, lack of quality assessment (QA) records (year 2021-2022) and interview with the laboratory director interview on September 8, 2022 at 11:45 a.m. it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on lack of syphilis serology quality control , manufacturer's instructions review (year 2021-2022) and laboratory director interview on September 8, 2022 , it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by Aim RPR method. The findings include: 1. The syphilis serology quality control records were requested to the laboratory director since february 2021. (reviewed on September 8, 2022 at 9: 20 a.m.) 2. The manufacturer's instruction establishes that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. (reviewed on September 8, 2022 at 9:25 a.m.) 3. From February 2021 to September 2022, the laboratory processed and reported 1,576 patient samples for RPR (rapid plasma reagin) and no quality control records were available in the laboratory. (reviewed on September 8, 2022 at 9:30 a.m.) 4. The laboratory director confirmed on September 8, 2022 at 11:00 AM, that the laboratory did not have available evidence of the syphilis serology quality control records.
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 lack of syphillis serology records, manufacturer's instructions review (year 2021-2022) and laboratory director interview on September 8, 2022, it was determined that the laboratory failed to perform syphillis serology test as required by

	manufacturer's instructions. The findings include: 1. The manufacturer's requires that the laboratory must perform the needle calibration, verify the rotator rpm and monitor the room temperature in the laboratory. (reviewed on September 8, 2022 at 9:20 a.m.) 2. Since february 2021 , the lack of records showed that the laboratory did not document nor verify the needle calibration, rotator rpm nor the room temperature monitoring in the RPR (Rapid plasma reagin) testing area. (reviewed on September 8, 2022 at 9:20 a.m.) 3. From february 2021 to september 2022, the laboratory processed and reported 1,576 patient samples for RPR (rapid plasma reaginforty seven (47) RPR (Rapid plasma reagin) patient's samples tests. 4. The laboratory director confirmed on September 8, 2022 at 11:00 AM, that the laboratory failed to perform syphillis serology test as required by manufacturer's instructions.
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 observation and laboratory director interview on September 8, 2022 , it was determined that the laboratory performed syphilis serology (Rapid plasma reagin) patient's test with control material and reagent that exceeded the expiration date. The findings include: 1. The laboratory performed syphilis serology test by RPR (Rapid plasma reagin) method. 2. The laboratory used the RPR reactive control , lot number 36150, expired on 09/01/2022 to perform RPR patient's samples since September 2022. (review on september 8, 2022 at 9:10 a.m.) 3. The laboratory used the RPR weakly reactive control, lot number 119303, expired on 09/01/2022 to perform RPR patient's samples since September 2022. (review on september 8, 2022 at 9:10 a.m.) 4. The laboratory used the RPR non reactive control, lot number 36130, expired on 09 /01/2022 to perform RPR patient's samples since September 2022. (review on september 8, 2022 at 9:10 a.m.) 5. The laboratory used the RPR reagent , lot number 1193010, expired on 09/01/2022 to perform RPR patient's samples since September 2022. (review on september 8, 2022 at 9:10 a.m.) 4. The laboratory processed and reported 22 RPR patient's samples the following days: 9/2/2022- 4 patient samples 9/3 /2022- 3 patient samples 9/6/2022- 11 patient samples 9/7/2022 -4 patient samples (review on september 8, 2022 at 9:15 a.m.) 5. The laboratory director confirmed on September 8, 2022 at 11:20 a.m. that the the laboratory performed syphilis serology (Rapid plasma reagin) patient's test with control material and reagent that exceeded the expiration date.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on laboratory area observation and laboratory director interview on September 8, 2022 at 9:00 a.m., it was determined that the laboratory failed to follow written

	instructions for the preventive maintenance of the Centrifuge and rotator instrument. The findings include: 1. The laboratory written procedures establishes that the laboratory must be verify the RPM of the centrifuge and verify the rotator annually. 2. During the survey performed on September 8, 2022 at 9:00 a.m., the surveyor observed that the last preventive maintenance of the Centrifuge and rotator instrument was perform in August 2020. 3. The laboratory director confirmed on September 8, 2022 at 10:10 a.m. that these preventive maintenance did not perform since August 2020.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) records (year 2021-2022) , QA procedure manual and laboratory director interview on September 8, 2022 at 11:50 a.m., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. (Refer to D5405, D5411, D5417and D5429.)
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assessment (QA) procedure manual review, lack of QA assessment records (year 2021-2022) and interview with the laboratory director interview on September 8, 2022 at 11:50 a.m. , it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: turn around time and the patient's final test reports.
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 lack of Puerto Rico Proficiency Testing records (PT) , Quality Assessment records QA) , syphilis serology quality control records and laboratory director interview at 11:30 a.m. on September 8, 2022, it was determined that the laboratory

	director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory records retention requirement, analytical system and QA requirements. The findings include: 1. The laboratory director did not comply with the Laboratory records retention requirements. Refer to D 6079 2. The laboratory director did not not comply with the syphilis serology quality control requirements. Refer to D 6093. 3. The laboratory director did not not comply with the QA requirements. Refer to D 6094.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on lack of Puerto Rico Proficiency Testing records (PT) , Quality Assessment records QA) , syphilis serology quality control records and laboratory director interview at 11:30 a.m. on September 8, 2022, it was determined that the laboratory director failed to ensure that the laboratory retain these records for at least 2 years. Refer to D3000.
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 lack of syphilis serology quality control records (year 2021-2022) and interview with the laboratory director on September 8, 2022 it was determined that the laboratory director did not assure that the laboratory follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by Aim RPR method. Refer to D5405 and D5429.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 lack Quality Assessment (QA) records review (year 2021-2022) and laboratory director interview on September 8, 2022 at 11:30 A.M., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment manual (2021-2022) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. (review on September 8, 2022 at 10:10 a.m.) 2. The laboratory director confirmed on September 8, 2022 at 11:30 A.M., that failed to evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. Refer to D5291 , D5391, D5791 and D5891.