Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1084371	01/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Costa Isabela	Carr Pr-459 Km 14 Hm 6 Bo Bejucos, Isabela, 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 records review (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 9:00 A.M., 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 December 2021. 2. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2020. 3. The laboratory testing personnel confirmed on January 21, 2022 at 9:00 A. M., that the laboratory director and testing personnel failed to sign the attestation statements since 2020.
D2067	SYPHILIS SEROLOGY CFR(s): 493.835(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

	This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 9:30 A.M., it was determined that the laboratory failed to participate in the syphilis serology first testing event performed in April 2021. The findings include: 1. Proficiency testing records were reviewed from February 2020 to December 2021. 2. The laboratory did not participate in the first testing event of syphilis serology performed in April 2021 established by the Proficiency Testing Program. 3. The laboratory testing personnel confirmed on January 21, 2022 at 9:30 A.M., that the laboratory failed to participate in the first testing event of syphilis serology sub-specialty in April 2021.
D2076	GENERAL IMMUNOLOGY CFR(s): 493.837(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 9:30 A.M., it was determined that the laboratory failed to participate in the General Immunology first testing event performed in April 2021. The findings include: 1. Proficiency testing records were reviewed from February 2020 to December 2021. 2. The laboratory did not participate in the first testing event of General Immunology (Rheumatoid Arthritis-RA) performed in April 2021 established by the Proficiency Testing Program. 3. The laboratory testing personnel confirmed on January 21, 2022 at 9:30 A. M., that the laboratory failed to participate in the first testing event of General Immunology sub-specialty in April 2021.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: 1. Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 9:45 A. M., it was determined that the laboratory failed to verify the accuracy of the hematology specialty when the PRPTP did not have hematology samples in the second testing event performed in June 2021. The findings include: a. . Proficiency testing records were reviewed from February 2020 to December 2021. b. In the Hematology second testing event performed in June 2021 , the State office sent to the laboratory a letter that oriented them that in absence of an event the regulation establishes that the laboratory must be verify the accuracy of the tests (platelet, white blood cells, red blood cells, hemoglobin, hematocrit) . c. The proficiency testing

	records showed that the laboratory did not verify the accuracy of the hematology specialty test in June 2021. d. The testing personnel on January 21, 2022 at 11:00 A. M. that the laboratory did not have a mechanism to verify the accuracy of the hematology tests. 2. Based on Puerto Rico Proficiency Testing Program records review (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 9:50 A.M., it was determined that the laboratory failed to verify the accuracy of the Rheumatoid arthritis (RA) and rapid plasma reagent (RPR) tests that received a zero score for nonparticipation. The findings include: a. Proficiency testing records were reviewed from February 2020 to December 2021. b. The deadline of the first testing event report of syphilis serology and general immunology tests was April 30, 2021. c. The proficiency testing records showed that the laboratory did not verify the accuracy of the Rheumatoid arthritis (RA) and rapid plasma reagent (RPR) tests that received a zero score for nonparticipation in April 2021. d. The testing personnel stated on January 21, 2022 at 10:00 A.M. that the laboratory did not have a mechanism to verify the accuracy of the syphilis serology and general immunology tests that received a zero score for nonparticipation on April 2021.
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 quality assessment (QA) records review and laboratory testing personnel interview on January 21, 2022 at 11:00 A.M., it was determined that the laboratory failed to have a mechanism to evaluate issues related to Proficiency testing performance. The findings include: 1. The quality assessment records were reviewed since January 2020. 2. The records showed that the laboratory did not have a mechanism used to evaluate and verify problems related to Proficiency Testing performance. Refer to D5215.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory final test report and laboratory testing personnel interview on January 21, 2021 at 11:30 A.M., it was determined that the laboratory failed to indicate the correct laboratory name in the hematology tests - Complete blood count (CBC) test results report. The findings include: 1. The laboratory testing

	personal stated on January 21, 2022 at 11:30 A.M. , that the Cell Dyn 3200 system was out of service since July 2021. 2. The laboratory testing personnel stated that occasionally the laboratory Costa Isabela I referred these tests to the Laboratory Costa Isabela II in Aguadilla (Clia # 40D2126781). 3. On January 21, 2022, the laboratory patient tests reports files were review by the surveyor (25 patient files) and showed that the laboratory perform and report the following CBC test: id sample date report 57567 9/7/2021 2245 9/14/2021 3186 10/15/2021 4. The laboratory testing personnel stated that these tests were perform on Laboratory Costa Isabela II- Aguadilla (Clia # 40D2126781) , however, the patient test result showed that this test was perform in Laboratory Costa Isabela II (Clia # 40D1084371) .
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 records review (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 12:30 P.M., it was determined that the laboratory failed to monitor problems identified in the post-analytic systems. (test report) The findings include: 1. The laboratory failed to indicate the correct laboratory name when perform CBC test results report . Refer to D5805.
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 Proficiency testing records reviewed (2020-2021) , personnel records review and laboratory testing personnel interview at 11:30 a.m. on January 21, 2022, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory proficiency testing , laboratory personnel and test report requirements. Refer to D 6089, D 6091, D 6094, D 6098 and D 6100.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 9:30 AM, it was determined that the laboratory director failed to ensure that proficiency testing

	samples were tested as required under Subpart H requirements. Refer to D2067 and D2076.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 10:00 A. M, it was determined that the laboratory director failed to evaluate the laboratory's performance in Proficiency testing and sign the attestation statements. Refer to D2009.
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 quality assessment records review (2020-2021) and laboratory testing personnel interview on January 21, 2022 at 12:30 P.M., it was determined that the laboratory failed to compliance with the requirement for post-analytic systems. The findings include: 1. The laboratory director failed to monitor and evaluate the requirements for general laboratory system and post analytic systems. Refer to D5291 and D5891.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on laboratory test results report (September - October 2021) and laboratory testing personnel interview on January 21, 2022 at 10:00 A. M, it was determined that the laboratory director failed to evaluate that test results include the correct information in the finals results. Refer to D 5805.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).

	This STANDARD is not met as evidenced by: Based on personnel records review (2021) and laboratory testing personnel interview on January 21, 2022 at 10:05 AM, it was determined that the laboratory director failed to fill the general supervisor position. The finding includes: 1. The personnel records showed that the General supervisor position was not filled from April 2021.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on testing personnel on January 21, 2022 at 12: 30 P.M. it was determined that the laboratory general supervisor position is not filled since April 2021. Refer to D6142.
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on testing personnel interview on January 21, 2022 at 12: 30 P.M. it was determined that the laboratory general supervisor position is not filled . The findings include: 1. On April 19, 2021 the laboratory change from moderate complexity laboratory tests to high complexity laboratory tests. 2. The testing personnel confirmed on January 21, 2022 at 12:30 P.M. that since the new laboratory director began on April 2021 the laboratory did not filled the position.