Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1060233	05/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Freytes	Calle 1 B 1-9 Villas De Loiza, Loiza, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2017 to February 2019 and laboratory general supervisor interview on May 9, 2019 at 9:22 AM, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for syphilis serology (Rapid Plasma Reagin - RPR) tests (Non-waived method) since January 3, 2018 to December 27, 2018. The findings include: 1. The laboratory processed and reported patients specimens for syphilis serology (RPR) tests by the Immuno RPR moderated method since January 3, 2018 to December 27, 2018. 2. The proficiency testing records showed that the laboratory failed to enrolled and participated in the proficiency testing samples for RPR tests since January 3, 2018 to December 27, 2018. 3. The laboratory general supervisor confirmed on May 9, 2019, that the laboratory not participated or enroll in HHS (Department of Health and Human Services) approved Proficiency Testing Program for RPR tests (Non Waived) from January 3, 2018 to December 27, 2019. 4. The laboratory processed and reported 1,016 out of 1,016 patients specimens for RPR tests by the Immuno RPR moderated method from January 3, 2018 to December 27, 2018.

D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2018 to March 2019 and laboratory general supervisor interview on May 9, 2019 at 9:25 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records were reviewed from February 2018 to March 2019. 2. Review of proficiency testing records from February 2018 to December 2018, showed that the laboratory did not maintain the following proficiency testing event records: November 2018, December 2018 and February 2019. 3. The laboratory general supervisor confirmed on May 9, 2019, that the laboratory did not maintain these proficiency testing event records.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review and laboratory general supervisor interview on May 9, 2019 at 9:25 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were reviewed from February 2018 to March 2019. 2. Review of proficiency testing records (PRPTP) showed that the laboratory obtained unsatisfactory results of 0 percent for Thyroid Stimulating Hormone (TSH), Thyroxine (T4), Triiodothyronine tests in February 2018 (PRPTP first testing event), 0 percent for Creatinine tests in June 2018 (PRPTP second testing event). No remedial actions were taken.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on endocrinology (Human Chorionic Gonadotropin - serum hCG) quality control records reviewed from January 14, 2019 to May 1, 2019 and laboratory general supervisor interview on May 9, 2019 at 11:00 AM, it was determined that the laboratory failed to perform the evaluation of the performance specifications of the endocrinology method (Aim Step Combo hCG). The findings include: 1. The laboratory begin to performed the serum hCG tests by Aim Step Combo method from January 14, 2019. 2. From January 14, 2019 to May 1, 2019, the quality control records showed that the laboratory did not verify the performance specifications of the new test for serum hCG. 3. The laboratory processed and reported 36 serum hCG tests from January 14, 2019 to May 1, 2019. 4. The laboratory general supervisor confirmed on May 9, 2019, that the laboratory did not perform the evaluation of performance specifications of the serum hCG (Aim Step Combo) method.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on hematology quality control records review and laboratory general supervisor interview on May 9, 2019 at 11:12 AM, it was determined that the laboratory failed to follow to evaluate twice a year the relationship of the WBC differential results between manual method and Coulter AcT 5 Diff AL system since January 4, 2018. The findings include: 1. The hematology quality control records showed that the laboratory did not evaluate the relationship of the WBC differential examination results (each six months) since January 4, 2018. 2. The laboratory general supervisor confirmed on May 9, 2019, that the laboratory did not evaluate twice a year the relationship of the WBC differential examination results performed by the manual method and Coulter AcT 5 Diff AL system.
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 quality assessment (QA) records review from 2017 to 2018 years and laboratory general supervisor interview on May 9, 2019 at 11:42 AM, it was determined that the laboratory failed to follow the Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The finding includes: 1. The laboratory did not evaluate aspects regarding: a. to follow the written policies to evaluate twice a year (each six months) the relationship of the WBC differential examination results performed by the manual method and Coulter AcT 5 Diff AL system. Refer to D5477.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on hematology quality controls records review and laboratory general supervisor interview on May 9, 2019 at 11:12 AM, it was determined that the laboratory failed to follow evaluate and define twice a year (each six months) the relationship between the automatic and manual calculation of the hematology media (MCV, MCH and MCHC) calculated values. The finding includes: 1. The laboratory general supervisor confirmed on May 9, 2019, that the laboratory failed to evaluate twice a year (each six months) the relationship between the automatic and manual calculation of the hematology media (MCV, MCH and MCHC) calculated values since January 4, 2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: 1. Based on proficiency testing record, syphilis serology (RPR) quality control, patient records review and laboratory general supervisor interview on May 9, 2019 at 9:12 AM, it was determined that the laboratory director failed to ensure that the it is enrolled in an HHS approved proficiency testing program for the syphilis serology tests (RPR) tests (Non-waived method) from January 4, 2018 to December 27, 2019. The finding includes: a. The laboratory director did not comply with the requirement of enrolled in an HHS approved proficiency testing program for syphilis serology tests (Non-waived method) from January 4, 2018 to December 27, 2018. Refer to D 6015.

	2. Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2018 to March 2019 and laboratory general supervisor interview on May 9, 2019 at 9:20 AM, it was determined that the laboratory director failed to follow a corrective action plan when the laboratory obtained an unsatisfactory result. Refer to D 6019.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) record, syphilis serology (RPR) quality control, patient records review and laboratory general supervisor interview on May 9, 2019 at 9:20 AM, it was determined that the laboratory director failed to ensure that the it is enrolled in an HHS approved proficiency testing program for the syphilis serology (RPR) tests (Non-waived method) from January 4, 2018 to December 27, 2018. Refer to D2000. (The laboratory processed and reported patients specimens for syphilis serology (RPR) tests (Non-waived method) from January 4, 2018 to December 27, 2018. However, the laboratory was not enrolled in an HHS-approved proficiency testing program for those tests.)
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2018 to March 2019 and laboratory general supervisor interview on May 9, 2019 at 9:20 AM, it was determined that the laboratory director failed to follow a corrective action plan when the laboratory obtained an unsatisfactory result. The finding includes: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were reviewed from February 2018 to March 2019. 2. Review of proficiency testing records (PRPTP) showed that the laboratory obtained unsatisfactory results of 0 percent for Direct Bilirubin, Thyroid Stimulating Hormone (TSH), Thyroxine (T4), Triiodothyronine, Microalbumin, Creatinine and Prostate Specific Antigen (PSA) tests in February 2018 (PRPTP first testing event), 0 percent for Direct Bilirubin, Microalbumin and Creatinine tests in June 2018 (PRPTP second testing event) and 0 percent for Prostate Specific Antigen (PSA) tests in October 2018 (PRPTP third testing event). No remedial actions were taken. Refer to D2094.

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 (QA) records review from 2017 and 2018 years and laboratory general supervisor interview on May 9, 2019 at 11:48 AM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The finding includes: 1. The laboratory did not evaluate the established Quality Asessment Program to monitor and evaluate the requirement for analytic systems. Refer to D5791.