Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658273	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Borinquen-Clinica Las Americas	Cond Clinica Las Americas, Hato Rey, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on hematology proficiency testing report review, verification of the Certification and Survey Provider Enhanced Reporting System (CASPER) report and interview with laboratory supervisor on July 12, 2023 at 8:53 AM; it was determined that the laboratory failed to take and document a corrective action when the laboratory obtained and unsatisfactory testing score of 60% in the hematology testing event for year 2022. The Findings include: a. On July 7, 2023 at 2:00 PM in the pre survey preparation the CASPER report from CMS showed that the laboratory obtained a testing score of 60% for the Whole Blood Cell (WBC). b. On July 12, 2023 at 8:48 AM the second proficiency testing event documentation of year 2022 was requested. The laboratory did not have any documentation related to the required testing event. c. On July 12, 2023 at 8:53 AM the laboratory supervisor confirmed that the laboratory did not have any remedial action other that the acquisition of a new testing instrument.
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) activities record review and interview with the laboratory supervisor on July 12, 2023 at 9:06 AM; it was determined that the laboratory fail to evaluate and monitor de general system requirements since January 2022. The findings include: a. On July 12, 2023 at 9:01 AM, the laboratory QA records were requested. The laboratory supervisor was not able to show the QA records evaluation for year 2022 and 2023. b. Since January 2022 the laboratory did not evaluate practices related to: patient confidentiality, specimen identification and integrity, complaint investigation and communications. c. The laboratory supervisor confirmed on July 12, 2023 at 9:06 AM that the general system QA evaluation were not evaluated for year 2022 and 2023.
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 (QA) activities record review and interview with the laboratory supervisor on July 12, 2023 at 9:06 AM; it was determined that the laboratory fail to evaluate and monitor the pre-analytic requirements since January 2022. The findings include: a. On July 12, 2023 at 9:01 AM, the laboratory QA was requested. The laboratory supervisor was not able to show the QA records for year 2022 and 2023. b. Sin January 2022 the laboratory did not evaluate practices related to: test request, specimen submission and handling, specimen referral. c. The laboratory general supervisor confirmed on July 12, 2023 at 9:06 AM that the pre-analytic system QA evaluations were not evaluated for year 2022 and 2023.
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 worksheet test record, patient's test result report, manufacturer's instruction and interview with the laboratory supervisor on July 12, 2023 at 10:59 AM; it was determined that the laboratory failed to follow the manufacturer's instruction related to the test result interpretation. The laboratory did not follow the manufacture's instruction when the reported two out of two serum pregnancy test on May 2, 2023 and February 16, 2023. The findings include: a. On July 12, 2023 at 10:48 AM the worksheet test report records of pregnancy test were reviewed. The records showed that two (2) patient's were reported as weakly positive. b. On July 12, 2023 at 10:52 AM the patient's final test results from May 2, 2023 and February 16, 2023 were requested, showing that the laboratory reported both patient's as weakly positive. c. On July 12, 2023 at 10:55 AM the manufacturer's instruction was requested. The manufacturer instructed to interpret the result as positive or negative. d. On July 12, 2023 at 10:59 AM the laboratory supervisor confirmed that in May 2, 2023 one out of

	two patient was reported as weakly positive and in February 16, 2023 one out of one patient was reported as weakly positive.
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 the Quality Assessment (QA) activities record review and interview with the laboratory supervisor on July 12, 2023 at 9:06 AM; it was determined that the laboratory fail to evaluate and monitor the analytic system requirements since January 2022. The findings include: a. On July 12, 2023 at 9:01 AM the laboratory QA was requested. The laboratory supervisor was not able to show the QA records for year 2022 and 2023. b. Since January 2022 the laboratory did not evaluate practices related to: equipment, instruments, reagents, materials, specimen and reagent storage conditions, system maintenance and function checks, verification of method performance specifications, calibration, control procedures, comparison of test results, test records and corrective actions. c. The laboratory supervisor confirmed on July 12, 2023 at 9:06 AM that the analytic system QA evaluations were not evaluated for year 2022 and 2023.
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) activities records review and interview with the laboratory general supervisor on July 12, 2023 at 9:06 AM it was determined that the laboratory fail to evaluated and monitor the post-analytic system requirements since January 2022. The findings include: a. On July 12, 2023 at 9:01 AM, the laboratory QA was requested. The laboratory supervisor was not able to showed the QA records for year 2022 and 2023. b. Since January 2022 the laboratory did not evaluate practices related to: test report and turn around time. c. The laboratory supervisor confirmed on July 12, 2023 at 9:06 AM that the post-analytic system QA evaluations were not evaluated for year 2022 and 2023.
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 Assessment (QA) records, proficiency record review, laboratory supervisor competency and interview with the laboratory supervisor on July 12, 2023 at 12:25 PM; it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure the compliance with the laboratory requirements. Refer to D6092, D6094 and D6103.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on proficiency testing report review, verification of the Certification and Survey Provider Enhanced Reporting System (CASPER) and laboratory supervisor interview on July 12, 2017 at 8:53 AM; it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory testing score of 60% in the hematology second testing event for the year 2022. Refer to D5211.
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 reviewed and laboratory supervisor interview on July 12, 2023 at 9:06 AM; it was determined that the laboratory director failed to ensure the compliance with QA requirements. Refer to D5291, D5391, D5791 and D5891.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel files and interview with the laboratory supervisor on July 12, 2023 at 12:15 PM, it was determined that the laboratory director did not evaluate the competence of the laboratory supervisor since January 2022. The findings include: a. On July 12, 2023 at 12:00 PM the laboratory supervisor records was reviewed and showed that no evaluation of the supervisor competence was included

	since January 2022. b. On July 12, 2023 at 12:15 PM the laboratory supervisor stated that no competence of his assigned duties and responsibilities as supervisor were performed since January 2022.