Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1093514	11/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Bahia	Ave Ponce De Leon # 125 Bo Amelia, Guaynabo, 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
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 patient test reports and laboratory general supervisor interview at 11: 00 a.m. on November 5, 2019, it was determined that the laboratory failed to keep copy of the original patient test reports. Refer D3041.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: 1. Based on lack of patient test reports and laboratory general supervisor interview on

	November 5, 2019 at 10:00 A.M., it was determined that the laboratory failed to retain a copy of the original patient test reports. The findings include: a. Patient samples test reports was requested from January 2018 to November 5, 2019. b. The laboratory performed approximately 34 patient samples during those months: Syphiis serology-1 Urinalysis-2 human chorionic hormone (hCG)-1 complete blood cell count- (CBC) 30 c. The laboratory did not have copy of patient's test reports that was performed during those months.
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 lack of Quality Assessment (QA) records (year 2018-2019) and laboratory general supervisor interview on November 5, 2019 at 10:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for pre- analytic systems. The findings include: 1. The laboratory did not evaluate the following QA assessment for pre- analytic systems from January 1, 2018: a. Test requests b. Specimen submission, c. Specimen handling. d. Specimen referral. 2. The laboratory general supervisor confirmed on November 5, 2019 at 10: 30 A.M., that the QA program was not evaluated since January 2018.
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 procedures manual, lack of quality assessment records (2018-2019) and laboratory general interview interview on November 5, 2019 at 10: 30 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post-analytic systems. The findings include: 1. Review of the quality assessment program showed that evaluations to patient's final test reports and turn around time (TAT) must be evaluated every year. 2. The laboratory general supervisor stated on November 5, 2019 at 10:30 A.M. that evaluations to patient's final test reports and turn around time were not performed since 2017.
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 patient test reports and laboratory general supervisor interview at 11: 00 a.m. on November 5, 2019, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory retention requirements. Refer D3041.
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 patient test results and laboratory general supervisor interview at 11: 30 a.m. on November 5, 2019, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory retention requirements. The finding includes: 1. The laboratory failed to retain a copy of the original patient test reports. Refer D3041.