Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0677932	08/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Caribe	Gautier Benitez #8, Cidra, 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
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 records review and laboratory director interview, it was determined that laboratory failed to evaluate and monitor the General Laboratory system requirements since January 2021. The findings include: a. On August 26, 2022 at 9:43 AM, the laboratory QA was requested. On August 26, 2022 at 11:19 AM the laboratory QA was requested again. No QA record was presented. b. Since January 2021 the laboratory did not evaluate practices related to: Patient confidentiality, specimen identification and integrity, compliant investigation, communications and personnel competency. c. The laboratory director confirmed on August 26, 2022 at 12:05 pm that the general laboratory QA evaluations were not available.
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) records and laboratory director interview, it was

	determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for pre-analytic systems. The findings include: a. On August 26, 2022 at 9:43 AM, the laboratory QA record was requested. On August 26, 2022 at 11:19 AM was requested again. No QA records was presented. b. Since January 2021 the laboratory did not evaluate practices related to: test request, specimen submission and handling, specimen referral. c. The laboratory director confirmed on August 26, 2022 at 12:05 PM, that the pre-analytic system QA evaluations were not available.
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 laboratory temperature records, manufacturer's instructions review and laboratory director interview it was determined that the laboratory did not monitor nor take any remedial actions when the temperature refrigerator charts showed were outside the manufacturer's inserts established ranges. The findings include: a. On August 26, 2022 at 11:00 AM, the laboratory refrigerator temperature records were review from January 7, 2021 to December 30, 2021. All documented temperature were within (9-10C) range. b. The manufacturer's inserts showed the following required storage temperature ranges: Chemistry (Vitros 250) reagents (2-8C); Rapid Plasma Reagin set (RPR) by Teco Diagnostics (2-8C); Mycoplasma IgM reagent Immunocard by Meridian (2-8C); Rheumatoid Factor a latex test (RA) by Teco Diagnostics (2-8C); C-Reactive Protein a latex test (CRP) by Teco Diagnostics (2-8C). c. The laboratory refrigerator temperature from January 1, 2022 to August 25, 2022 was requested and was not presented. However no refrigerator temperature records were showed during the survey. d. The laboratory director confirmed on August 26, 2022 at 12:20 PM, that since January 7, 2021 to December 30, 2021 the temperature was documented out of range (9-10C).
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 and laboratory director interview, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for analytic systems. The findings include: a. On August 26, 2022 at 9:43 AM, the laboratory QA record was requested. On August 26, 2022 at 11: 19 AM was requested again. No QA records was presented. b. Since January 2021 the laboratory did not evaluate practices related to: test procedures, accurate and reliable test system, 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, corrective actions. c. The laboratory director confirmed on August 26, 2022 at 12:05 PM, that the analytic system QA evaluations were not available.
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) records and laboratory director interview, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for post-analytic systems. The findings include: a. On August 26, 2022 at 9:43 AM, the laboratory QA record was requested. On August 26, 2022 at 11:19 AM was requested again. No QA records was presented. b. Since January 2021 the laboratory did not evaluate practices related to: test report, and turn around time c. The laboratory director confirmed on August 26, 2022 at 12:05 PM, that the post-analytic system evaluations QA were not available.
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 control records review, quality assesment and laboratory supervisor interview on August 26, 2022 at 12:30 pm, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D 6094.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on laboratory temperature records, manufacturer's instructions review and laboratory director interview it was determined that the laboratory director fail to fulfill his responsibilities to monitor or take any remedial actions when the temperature refrigerator charts showed were outside the manufacturer's inserts established ranges. Refer to D 5411.
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 director failed to ensure compliance with QA requirements. Refer to D5291, D5391, D5791 and D5891.