Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0667081	12/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Medico	31 Mayor, Ponce, 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 lack of Quality Assessment (QA) activities records and laboratory director interview, it was determined that laboratory failed to evaluate and monitor the General Laboratory system requirements since January 2022. The findings include: a. On December 20, 2022 at 9:50 AM, the laboratory QA was requested. No QA record was available. b. Since January 2022 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 December 20, 2022 at 9:50 AM that the general laboratory system QA evaluation 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 lack of Quality Assessment (QA) activities records and laboratory director interview, it was determined that laboratory failed to evaluate and monitor the pre-

	analytic systems requirements since January 2022. The findings include: a. On December 20, 2022 at 9:50 AM, the laboratory QA was requested. No QA record was available. b. Since January 2022 the laboratory did not evaluate practices related to: test request, specimen submission and handling, specimen referral. c. The laboratory director confirmed on December 20, 2022 at 9:50 AM that the pre-analytic systems QA evaluation were not available.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Syphilis Serology (Rapid Plasma Reagin (RPR)) quality control records review (years 2021 to 2022) and interview with the laboratory director, it was determined that the laboratory did not include each day of testing the reactive nor the non reactive control materials when 11 out of 11 patients specimens were tested and reported for RPR on September 7, 2022. The findings include: 1. The laboratory use Immunostic RPR Card testing method to perform the Syphilis qualitative test. 2. On December 20, 2022 at 8:50 AM, review of syphilis quality control record showed that the laboratory did not include each day of testing the reactive nor the non reactive control materials on September 7, 2022. 3. The laboratory director confirmed on December 20, 2022 at 9:06 AM, that the laboratory failed to include each day of patient testing the reactive and non reactive control material on September 7, 2022. 4. The laboratory processed and reported 11 out 11 patient samples for Syphilis (RPR) qualitative tests without controls on September 7, 2022
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 lack of Quality Assessment (QA) activities records and laboratory director interview, it was determined that laboratory failed to evaluate and monitor the analytic systems requirements since January 2022. The findings include: a. On December 20, 2022 at 9:50 AM, the laboratory QA was requested. No QA record was available. b. Since January 2022 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 ations. c. The laboratory director confirmed on December 20, 2022 at 9:50 AM that the analytic systems QA evaluation 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 lack of Quality Assessment (QA) activities records and laboratory director interview, it was determined that laboratory failed to evaluate and monitor the post-analytic systems system requirements since January 2022. The findings include: a. On December 20, 2022 at 9:50 AM, the laboratory QA was requested. No QA record was available. b. Since January 2022 the laboratory did not evaluate practices related to: test report and turn around time. c. The laboratory director confirmed on December 20, 2022 at 9:50 AM that the post-analytic systems QA evaluation were not available.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 Syphilis Serology (RPR (rapid reagin plasma)) quality control records review, and interview the laboratory director on December 20, 2022 at 10:15 AM, it was determined that the laboratory director failed to follow the quality control procedures for the RPR. Refer to D 5449.
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 lack of Quality Assesstment (QA) records and laboatory director failed to evaluate and monitor the QA requirements. Refer to D5291, D5391, D5791 and D5891.