Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1086669	08/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Gordo Iii	Centro Comercial Alto Apolo Calle Sirce Esq Ave, San Juan, 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 assurance program, laboratory personnel competence records review and laboratory director interview on August 10, 2018 at 8:40 AM, it was determined that the laboratory failed to follow written protocol to assess the general laboratory system requirements. The findings include: 1. The quality assurance program establishes to perform an annual competence for the laboratory personnel. 2. On August 10, 2018 at 8:40 AM, the laboratory personnel competence records showed that the laboratory did not evaluate annually the performance of the general supervisor since August 2016. The laboratory evaluated annually the general supervisor as testing personnel. 3. The laboratory director confirmed on August 10, 2018 at 8:40 AM, that the laboratory did not evaluate this personnel for the general supervisor responsibility.
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 assurance (QA) program, QA activity records (years 2017, 2018) review, direct observation of sedimentation rate (SR) reporting results and general supervisor interview on August 10, 20-18 at 10:00 AM, it was determined that the laboratory failed to establish and follow a written protocol to assessing practices related to SR test reports from January 10, 2018 to August 10, 2018. The findings includes: 1. August 10, 20-18 at 10:00 AM, it was observed that the laboratory processed the SR patients specimens by the Sedimat system. The laboratory documented the patients SR results in the label of the patients sample collection tube. In the label of the first SR patient specimen of the day, the testing personnel also documented the values of the two control materials. Later, the testing personnel manually entered the data of the quality control to the laboratory information system (LIS) and entered manually the data of SR patients results to report by the LIS. All label of the patients collections tube were discarded. 2. The general supervisor confirmed on August 10, 20-18 at 10:00 AM, the SR practices related to SR test reports from January 10, 2018 to August 10, 2018. 3. The QA activity records showed no activity to assessing those practices related to SR test reports since January 2018. 4. The laboratory processed and reported 354 out of 354 patients specimens from January 10, 2018 to August 10, 2018.
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 assurance program, laboratory personnel competence records(years 2016 to 2018), QA activity records review (2017, 2018) records review, direct observation of sedimentation rate (SR) reporting results, laboratory director and general supervisor on August 10, 20-18 at 10:00 AM, it was determined that the laboratory director failed to comply with the QA requirements. Refer to D 5291 (The laboratory failed to perform the competence of the general supervisor). Refer to D 5891 (The laboratory failed to establish and follow a written protocol to assessing practices related to SR test reports).