Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0667128	12/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Irizarry Guasch	99 Central, Carr 14 Bo Coto Laurel, Coto Laurel, 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
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 procedure manual, quality assessment records review (year 2017 and 2019) and interview with the laboratory general supervisor on December 4, 2019 at 9:20 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests The findings include: a. Review of the quality assessment program showed that the laboratory must evaluate the patient's test requests every year. b. Review of the quality assessment records on December 4, 2019 at 9:35 AM, showed that the last evaluation to patient test requests was performed during year 2017. c. The laboratory general supervisor state that evaluations to test requests scheduled for year 2018 and 2019 were not performed.
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 procedure manual, quality assessment records review (year 2017 and 2019) and interview with the laboratory general supervisor on

	December 4, 2019 at 9:35 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: final patient's test results. The findings include: a. Review of the quality assessment program showed that the laboratory must evaluate the final patient's test results every year. b. Review of the quality assessment records on December 4, 2019 at 9:35 AM, showed that the last evaluation to final patient's test results was performed during year 2017. c. The laboratory general supervisor state that evaluations to final patient's test results scheduled for year 2018 and 2019 were not performed.
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 review and laboratory general supervisor interview on December 4, 2019 at 9:20 AM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The finding includes: a. Quality Assessment records showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for preanalytic and postanalytic systems. Refer to D5391 and D5891.