Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0669530	02/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Los Robles	#308 Americo Miranda Ave, Rio Piedras, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on facility records review and laboratory general supervisor interview at 9:55 AM on February 5, 2020, it was determined that the laboratory failed to be in compliance with the Puerto Rico State laboratory regulation. The findings include: 1. The laboratory Biomedical Generator Number was due since January 9, 2020. 2. The laboratory director confirmed on February 5, 2020, that the Biomedical Generator Number was due since January 9, 2020.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of clinical consultant records and laboratory director interview at 10: 12 AM on February 5, 2020, it was determined that the laboratory failed to follow written policies to assess the Clinical Consultant (MD # 13552) competency. The findings include : 1. Clinical Consultant records were reviewed since November 2018. 2. The laboratory director failed to perform the annual competency evaluation to the Clinical Consultant (MD #13552) since November 2018.

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) records review from January 2018 to December 2019 and laboratory director interview on February 5, 2020 at 10:12 AM, it was determined that laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for general laboratory systems. The findings include: 1. The laboratory quality assessment records showed that Clinical Consultant personnel competence must be performed every year. 2. The laboratory did not evaluate the Clinical Consultant (MD # 13552) competence since November 2018. Refer to D5209.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on facility records review (from January 1, 2018 to February 5, 2020) and laboratory director interview at 9:55 AM on February 5, 2020, it was determined that the laboratory director failed to be in compliance with the Puerto Rico State laboratory regulation. The finding includes: 1. The laboratory Biomedical Generator Number was due since January 9, 2020. Refer to D3009.