Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658026	07/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Bayamon	Edif Estacionamiento Joaquin Montesino, Bayamon, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing records review (2018-2019) and laboratory general supervisor interview on July 30, 2019 at 9:20 A.M., it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2018 to June 2019. 2. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2018. 3. The laboratory general supervisor confirmed on July 29, 2019 at 9:20 A.M that the laboratory director and testing personnel failed to sign the attestation statements since 2018.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on reviewed of quality assessment records (year 2018-2019) and laboratory general supervisor interview on July 30, 2019 at 9:30 A.M, it was determined that the laboratory failed to follow written procedures to ensure confidentiality of patient

	information throughout all phases of the testing process that are under the laboratory control. The findings include: 1. The laboratory did not perform in 2018 and 2019 an evaluation to ensure confidentiality of patient information throughout all phases of the testing process that are under the laboratory control. 2. The laboratory general supervisor confirmed on July 30, 2019 at 9:30 A.M., that in from January 2018 to June 2019 the laboratory did follow written procedures to ensure confidentiality of patient information and failed to perform an evaluation to ensure confidentiality of patient information.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) written procedures review (year 2018-2019) and laboratory general supervisor interview on July 30, 2019 at 9:40 AM, it was determined that the laboratory failed to follow written procedures to document and evaluate any complaint submitted and problems reported. The findings include: 1. Quality Assessment (QA) written procedures were reviewed from 2018-2019. 2. Since January 2018 the laboratory did not document or evaluate any complaint submitted to the laboratory. 3. The laboratory general supervisor confirmed on July 30, 2019 at 9: 40 A.M., that the laboratory did not document or evaluate any complaint submitted to the laboratory since 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 reviewed of quality assessment records (year 2018-2019) , and laboratory general supervisor interview on July 30, 2019 at 9:45 AM, it was determined that the laboratory failed to follow Quality Assessment Program to monitor and evaluate the following requirements for general laboratory systems: confidentiality of patient information and complaint. The findings include: 1. The laboratory failed to follow written procedures to ensure confidentiality of patient information . Refer to D 5201. 2. The laboratory failed to follow written procedures in order to evaluate and document any complaint. Refer to D 5205. 3. The laboratory general supervisor confirmed on July 30, 2019 at 9:45 A.M., that evaluations to confidentiality of patient information and complaint were not performed since 2018.
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 reviewed of Quality Assessment (QA) written procedures (year 2018-2019) and laboratory general supervisor interview on July 30, 2019 at 9:45 AM, it was determined that the laboratory failed to follow Quality Assessment Program to monitor and evaluate the requirement for pre- analytic systems. The findings include: 1. Quality Assessment (QA) written procedures were reviewed from 2018-2019. 2. The laboratory did not evaluate the following QA assessment for pre- analytic systems. since 2018: test requests 3. The laboratory general supervisor confirmed on July 30, 2019 at 9:45 A.M., that the pre analytic system was not evaluated since 2018.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency testing records review (year 2018-2019) and laboratory general supervisor interview on July 30, 2019 at 10:30 A.M., it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2009.
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 (year 2018-2019) and laboratory general supervisor interview on July 30, 2019 at 10:00 A.M. it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems and preanalytic systems. 2. The laboratory general supervisor confirmed on July 30, 2019 at 10:00 A.M., that the laboratory failed to evaluate the requirements for laboratory general systems and preanalytic systems. Refer to D5291 and D5391.