Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658298	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Risan	Ave Roberto Sanchez Vilella Urb Country Club, Carolina, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of quality assessment (QA) records review (years 2020-2021) and laboratory testing personnell on July 22, 2021 at 10:15 AM, it was determined that the laboratory failed to ensure compliance with the laboratory general system requierements. Refer to D5291.
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 lack of quality assessment (QA) records review (years 2020-2021) and laboratory testing personnell interview on July 22, 2021 at 10:15 Am, it was determined that the laboratory failed to follow written procedures to ensure confidentiality of patient information throughout all phases of the total testing process that are uder the laboratory's control. The findings include: 1. The laboratories written

	procedures require an annual evaluation, to ensure to follow protocol of the confidentiality of patient information throughout all phases are under the laboratory's control. 2. The laboratory did not perform the annuall monitory as written procedures required. The last monitoring was performed in year 2019. 3. The laboratory testing personnel confirmed on July 22, 2021 that the laboratory failed to follow written procedures to ensure confidentiality of patient information throughout all phases since 2019.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on lack of quality assessment records (years 2020-2021), quality assessment (QA) written procedures review and laboratory testing personnel interview on July 22, 2021 at 10:15 AM, it was determined that the laboratory failed to follow the written procedures to ensure the positive identification and optimum integrity of patient specimen from the time of collection or receipt through completion of testing and reporting of results. The findings include: 1. The laboratory written procedures establishes that the specimen identification and optimum integrity must be evaluated annually. 2. The laboratory testing personnel stated on July 22, 2021, that the laboratory did not perform an evaluation to ensure positive identification and optimum integrity of a patient's specimen that are under the laboratory control since December 2019.
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, lack of quality assessment records (years 2020-2021) and laboratory testing personnel interview on July 22, 2021 at 10:15 AM, it was determined that the laboratory failed to follow the written procedures to document and evaluate any complaint submitted and problems reported. The findings include: 1. Quality Assessment (QA) written procedures were reviewed on the survey performed on July 22, 2021. 2. The laboratory did not document or evaluate any complaint submitted to the laboratory since December 2019. 3. The laboratory testing personnel confirmed on january 22, 2021, that the laboratory did not document or evaluate any complaint submitted to the laboratory since December 2019.
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 written procedures review, lack of quality assessment records review (years 2019-2021) and laboratory personnel testing interview on July 22, 2021 at 10:15 AM, it was determined that the laboratory failed to follow the weitten procedures to monitor and evaluate the following QA activities since December 2019: 1. Patient Confidentiality (D5202) 2. Specimen identification and integrity (D5203) 3. Complaint Investigation (D5205)
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 calendar, lack of quality assessment recordsyears 2020 and 2021) and laboratory testing personnel interview on July 22, 2021 at 10:15 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for pre analytic laboratory systems: test request. The findings include: 1. Review of the quality assessment procedure manual showed that evaluations to test requisitions must perform anually (august). 2. Review of the quality assessment records showed that the laboratory did not evaluate the test requisitions since august 2019. 3. The laboratory testing personnel confirmed on July 22, 2021 at 10:15 A.M. that evaluations to test requisitions were not performed since august 2019.
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 quality assessment procedure manual, quality assesment (QA) records review(years 2019 and 2021), laboratory testing personnel interview on July 22 2021 at 10:15 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment calendar, the records showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. 2. Since December 2019, the quality assessment (QA) records showed that the laboratory did not perform the yearly per work area (december) evaluation of the analytic system. 3. The

	laboratory testing personnel confirmed on July 22, 2021 at 10:15A.M., that the laboratory failed to perform the yearly per work area (december) evaluation of the analytic system.
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 (QA) procedure manual, quality assessment records review (year 2019 and 2021) and interview with the laboratory testing personnel interview on July 22, 2021 at 10:15 aM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: turn around time and completeness of the patient's final test reports. The findings include: 1. Review of the quality assessment program on July 22, 2021 at 10:15 AM, showed that evaluations related to the laboratory turn around time must be evaluated every year during the month of October. The evaluations and findings , if any, must be documented in the QA records. 2. Review of the quality assessment record showed that the last turn around time evaluation was performed in October 2019. 3. Review of the quality assessment program, on July 22, 2021 at 10:15 AM, showed that evaluations related to the completeness of the patient's final test reports must be evaluated every year during the month of August. The evaluations and findings , if any, must be documented in the QA records 4. Review of the quality assessment record showed that the last evaluation was performed in August 2019.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on quality assessment procedure manual, quality assessment (QA) records review and laboratory testng personnel interview at 10:30 AM on July 22, 2021, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality assessment requirements. Refer to D 6094.
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 (years 2019-2021) and laboratorytesting personnell interview on July 22, 2021 at 10:15 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, preanalytic, analytic and postanalytic systems. 2. The laboratory testing personnell confirmed on July 22, 2021 at 10:15 AM, that failed to evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. Refer to D5200, D5291 , D5391, D5791 and D5891.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on personnel records review (years 2019-2021) and laboratory testing personnell interview at 10:30 AM on July 22, 2021, it was determined that the laboratory failed to follow the established schedule for clinical consultant evaluation. The findings include: 1. The laboratory schedule for clinical consultant competence evaluation showed that it must be performed every year. 2. The laboratory did not perform the clinical consultant competence evaluation since December 2019. 3. The testing personnell confirmed that the competence evaluation were not performed as established.