Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658298	11/15/2019
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
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 (QA) procedure manual, quality assessment records review (year 2018 and 2019) and interview with the laboratory general supervisor interview on November 15, 2019 at 12:30 PM, 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 evaluations to patient test request must be evaluated every year during the month of August. b. Review of the quality assessment records on November 15, 2019 at 12:30 PM, showed that the last evaluation to the patient's test requests was performed in August 2018. c. The laboratory general supervisor stated that evaluations to test requests scheduled for August 2019 was not performed
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 (QA) procedure manual, quality assessment records review (year 2018 and 2019) and interview with the laboratory general supervisor interview on November 15, 2019 at 12:30 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: comparison of test results. The findings include: a. The laboratory performed and reported white blood cells differential counts by the Coulter Act-5 Diff and also performed manual slide screenings.. b. Review of the quality assessment program on November 15, 2019 at 12: 30 PM, showed that evaluations related to comparison of test results (white blood cell differential count) must be evaluated every six months (May and November of each year). The evaluations and findings , if any, must be documented in the QA records. c. Review of the quality assessment records showed that the last evaluation was performed in November 2018. d. Review of the quality assessment program, on November 15, 2019 at 12:30 PM, showed that evaluations related to comparison of test results (inconsistent tests) must be evaluated every year. The evaluations and findings , if any, must be documented in the QA records e. Review of the quality assessment records showed that the last evaluation was performed in year 2017. f. The laboratory supervisor stated on November 15, 2019 at 1:45 PM that the evaluations 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 (QA) procedure manual, quality assessment records review (year 2018 and 2019) and interview with the laboratory general supervisor interview on November 15, 2019 at 1:40 PM, 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: a. Review of the quality assessment program on November 15, 2019 at 1:40 PM, showed that evaluations related to the laboratory turn around time must be evaluated every year during the month of February. The evaluations and findings , if any, must be documented in the QA records. b. Review of the quality assessment record showed that the last turn around time evaluation was performed in February 2018. c. Review of the quality assessment program, on November 15, 2019 at 1:40 PM, 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 d. Review of the quality assessment record showed that the last evaluation was performed in August 2019. e. The laboratory supervisor stated on November 15, 2019 at 1:45 PM that the evaluations 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 November 15, 2019 between 12:30 to 1:45 PM, it was determined that laboratory director did not ensure compliance with quality assessment (QA) requirements. The findings include: a. The Quality Assessment records showed that the laboratory director did not evaluate the scheduled requirements for preanalytic, analytic and postanalytic systems. b. The general supervisor stated that the requirements were not evaluated by the laboratory director. Refer to D5391, D5791 and D5891.