Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2037156	01/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Tiago	Urbanizacion San Feliz Calle 1 , A-2, Corozal, 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 (2020-2021) and laboratory general supervisor interview on January 25, 2022 at 10:00 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: a. Review of the quality assessment procedure manual showed that evaluations to test requisitions must perform each 6 months. b. Review of the quality assessment records showed that the laboratory did not evaluate the test requisitions since April 2020 c. The laboratory general supervisor confirmed on January 25, 2022 at 10:00 AM. that evaluations to test requisitions were not performed since April 2020.
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 procedures manual, quality assessment records review (2020-2021) and laboratory general supervisor interview on January 25, 2022 at 10:00

	A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post-analytic systems. The findings include: a. Review of the quality assessment program showed that evaluations to patient's final test reports and turn around time (TAT) must be evaluated every six month. b. Review of the quality assessment records showed that the last evaluations to patient's final test reports and turn around time was performed in August 2020. c. The laboratory general supervisor stated on January 25, 2022 at 10: 00 A.M., that evaluations to patient's final test reports and turn around time were not performed since August 2020.
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 (2020-2021) and laboratory general supervisor interview on January 25, 2022 at 10:15 A.M, it was determined that laboratory director 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 preanalytic and postanalytic systems. 2. The laboratory general supervisor confirmed on January 25, 2022 at 10:15 A.M , that the laboratory director failed to evaluate the requirements for laboratory preanalytic and postanalytic systems. Refer to D5391 and D5891.