Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0966252	10/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Frontera	Calle Mendez Vigo Num 110 Esq Martinez Nadal, Mayaguez, 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 (in years 2021-2022) and laboratory general supervisor interview at 9:00 AM on October 28, 2022, 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 (DBR-RM-50-14-02-0101) was due since October 23, 2022. 2. The laboratory general supervisor confirmed on October 28, 2022 at 9:00 A.M., that the laboratory not renew the new Biomedical Generator Number. 3. The state law establishes that the Biomedical Generator Number must be renew 60 days before the expired date.
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 (QA) records review (year 2021-2022) and interview with the laboratory general supervisor interview on October 28, 2022, 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: 1. Review of the quality assessment program showed that evaluations to patient test request must be evaluated biannually. (review on October 28, 2022 at 10:30 a.m.) 2. Review of the quality assessment records showed that the last evaluation to patient test requests was performed in May 2021. (review on October 28, 2022 at 10:30 a.m.) 3. The laboratory general supervisor confirmed that evaluations to test requests scheduled for performed biannually was not performed. (review on October 28, 2022 at 10:35 a.m.)
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, QA assessment records review (year 2021-2022) and interview with the laboratory general supervisor interview on October 28, 2022, 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 the patient's final test reports. The findings include: 1. Review of the quality assessment program showed that evaluations related to the laboratory turn around time and the patient's final test reports. must be evaluated biannually. (review on October 28, 2022 at 10:40 a.m.) 2. Review of the quality assessment record showed that the last turn around time and patient's final test reports evaluation was performed in June 2021. (review on October 28, 2022 at 10:40 a.m.) 3. The laboratory general supervisor confirmed on October 28, 2022 at 10:45 a.m. , that the laboratory failed to perform the evaluations of turn around time and the patient's final test reports.
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 2021-2022) and laboratory general supervisor interview on October 28, 2022 at 11:15 A.M., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records (2021-2022) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory preanalytic and postanalytic systems. (review on October 28, 2022 at 11:20 a.m.) 2. The laboratory general supervisor confirmed on October 28, 2022 at 11: 25 a..m. , that failed to evaluate the requirements for laboratory preanalytic and postanalytic systems. Refer to D5391 and D5891.