Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0898403	12/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clin Asociacion Maestros De Pr	Calle Ramos Antonini 158 Este, 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
D0000	An announced CLIA Recertification survey was conducted at the Laboratorio Clnico Asociacion de Maestros on December 10, 2024 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: D5291 General Laboratory Systems Quality Assessment CFR(s): 493.1239 (a) D5391 PreAnalytic Systems Quality Assessment CFR(s): 493.1249 (a) D5791 Analytic Systems Quality Assessment CFR(s): 493.1289 (a)(c) D5891 Postanalytic Systems Quality Assessment CFR(s): 493.1299 (a)
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 (QA) program review (years 2023-2024) and laboratory general supervisor interview on December 10, 2024, at 11:00 A.M., it was determined that the laboratory failed to follow the established QA program to monitor and evaluate the following requirements for General laboratory systems: patient confidentiality, specimen identification and integrity, complaint investigations and communications. The findings include: 1. On December 10, 2024, 2024, at 10:00 A. M., review of the laboratory QA program showed that: a. Patient confidentiality must be evaluated annually; the record showed that the last evaluation was performed in January 2023. b. Specimen identification and integrity must be evaluated with each event that occurs, and annually; the record showed that the last evaluation was performed on June 15, 2023. c. Complaint investigations, must be evaluated monthly; the record showed that the last evaluation was performed in December 2023. d. Communications must be evaluated with each event that occurs; the record showed

	that the last evaluation was performed in January 2023. 2. The laboratory general supervisor confirmed during interview on December 10, 2024, at 11:30 A.M., that the general systems QA evaluations were not performed during year 2024.
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) program review (years 2023-2024) and interview with the laboratory general supervisor interview on December 10, 2024, at 11:07 A. M., it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests and specimen submission, handling and referral. The findings include: 1. On December 10, 2024, 2024, at 11:07 A.M., review of the laboratory QA program showed that: a. Patient test requests must be evaluated every six months; the record showed that the last evaluation was performed on December 28, 2023. b. Specimen submission, handling and referral must be evaluated annually; the record showed that the last evaluation was performed on October 25, 2023. 2. The laboratory general supervisor confirmed during interview on December 10, 2024, at 11:30 A.M., that the preanalytic systems QA evaluations were not performed during year 2024.
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) program review (years 2023-2024) and interview with the laboratory general supervisor interview on December 10, 2024, at 11:12 A. M., it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for analytic systems: comparison of test results and test records. The findings include: 1. On December 10, 2024, 2024, at 11:12 A.M., review of the laboratory QA program showed that: a. Comparison of test results must be evaluated every six months; the record showed that the last evaluation was performed on December 9, 2023. b. Specimen submission, handling and referral must be evaluated annually; the record showed that the last evaluation was performed on June 22, 2023. 2. The laboratory general supervisor confirmed during interview on December 10, 2024, at 11:30 A.M., that the analytic systems QA evaluations were not performed during year 2024.
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) program review (years 2023-2024) and interview with the laboratory general supervisor interview on December 10, 2024, at 11:17 A. M., it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for postanalytical systems: patient test reports and turn around time (TAT). The findings include: 1. On December 10, 2024, 2024, at 11:17 A.M., review of the laboratory QA program showed that: a. Patient test reports must be evaluated annually; the record showed that the last evaluation was performed in December 2023. b. TAT must be evaluated annually; the record showed that the last evaluation was performed in December 2023. 2. The laboratory general supervisor confirmed during interview on December 10, 2024, at 11:30 A.M.,that the postanalytic systems QA evaluations were not performed during year 2024.
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 QA program review and interview with the laboratory general supervisor on December 10, 2024, at 11:30 A.M., it was determined that the laboratory director failed to ensure that the technical supervisor evaluated, as required, the QA activities. Refer to D6117.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on QA program review and interview with the laboratory general supervisor on December 10, 2024 at 11:30A.M., it was determined that the laboratory technical supervisor failed to fulfill her responsibility to ensure that the QA activities was evaluated, as required, in the year 2024. Refer to D5291, D5391, D5791 and D5891.