Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1077716	03/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Paseo Del Rio	Carretera Num 183 Km 4 Hm 8 Bo Tomas De Castro, Caguas, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on laboratory competence schedule, personnel file review and interview with the laboratory supervisor on March 5, 2024 at 9:23 AM; it was determined that the laboratory failed to follow the estabiched schedule for the testing personnel competence (MT #6208) since December 2021. The findings include: a. On March 5, 2024 at 9:00 AM, the competence schedule was reviewed. The schedule showed that the testing personnel competence must be performed every year. b. On March 5, 2024 at 9:15 AM, the personnel files was review and showed that the laboratory did not performed the testing personnel competence, for MT #6208, since December 2021. c. On March 5, 2024 at 9:23 AM, the laboratory supervisor confirmed that the testing personnel, MT #6208, competence was not performed since December 2021.
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) activities records review and laboratory supervisor interview on March 5, 2024 at 10:30 AM, it was determined that the laboratory failed to evaluate and monitor the complaint investigation in the General Laboratory system since June 2023. The findings include: a. On March 5, 2024 at 10: 00 AM, the laboratory QA was requested. The QA showed that the laboratory has established that the laboratory complaint investigation were evaluated in June and December. b. On March 5, 2024 at 10:15 AM the QA showed that the laboratory failed to evaluate and monitor the complaint investigaton since June 2023. c. The laboratory general supervisor confirmed on March 5, 2024 at 10:30 AM that the laboratory failed to evaluate and monitor the complaint investigation since June 2023.
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) records and laboratory supervisor interview on March 5, 2024 at 10:30 AM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for pre-analytic systems. The findings include: a. On March 5, 2024 at 10:00 AM, the laboratory QA was requested. The QA showed that the laboratory has established that the laboratory evaluation of medical record and requisiton test, and referred samples were evaluated in June and December. b. On March 5, 2024 at 10:15 AM the QA showed that the laboratory failed to evaluate and monitor the evaluation of medical record and requisiton test, and referred samples since June 2023. c. The laboratory general supervisor confirmed on March 5, 2024 at 10:30 AM that the laboratory failed to evaluate and monitor the evaluation of medical record and requisiton test, and referred samples since June 2023.
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) records and laboratory supervisor interview on March 5, 2024 at 10:30 AM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for post-analytic systems. The findings include: a. On March 5, 2024 at 10:00 AM, the laboratory QA was requested. The QA showed that the laboratory has established that the laboratory evaluation of result reported, Turn around time and comparison of manual results versus system were evaluated in June and December. b. On March 5, 2024 at 10:15 AM the QA showed that the laboratory failed to evaluate and monitor the evaluation of result reported, Turn around time and comparison of manual results versus system

	since June 2023. c. The laboratory general supervisor confirmed on March 5, 2024 at 10:30 AM that the laboratory failed to evaluate and monitor the result reported, Turn around time and comparison of manual results versus system since June 2023.
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 Assesstment (QA) records reviewed and interview with the laboatory supervisor on March 5, 2024 at 10:30 AM; it was determined that the laboratory director failed to ensure the compliance with QA requirements for year 2023. Refer to D5291, D5391 and D5891.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory supervisor interview on March 5, 2024 at 9:23 AM, it was determined that the laboratory failed to follow the established schedule for testing personnel competence evaluation. Refer to D5209.