Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1049944	06/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Fajardo	Carr #3 Int Carr 194 Local, Suite 100, Fajardo, 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	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Fajardo on June 11, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on June 11, 2026.
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 lack of Quality Assessment (QA) activities records (years 2025-2026) and interview with the laboratory director on June 11, 2026 at 12:55 PM, the laboratory failed to evaluate and monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance since January 2025. The findings include: 1. On June 11, 2026 at 12:55 PM, the laboratory general system QA 2025-2026 records were requested. The general system QA was not available for evaluation. 2. The laboratory director confirmed on June 11, 2026 at 1:02 PM, that the laboratory QA general system activities records were not available in the laboratory, and that the laboratory failed to monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance since January 2025.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1249(a) (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 lack of Quality Assessment (QA) activities records (years 2025-2026) and interview with the laboratory director on June 11, 2026 at 12:55 PM, the laboratory failed to evaluate and monitor the pre-analytic laboratory systems related to: patient test requests, specimen submission, handling and referral, since January 2025. The findings include: 1. On June 11, 2026 at 12:55 PM the laboratory pre-analytic system QA 2025-2026 records were requested. The pre-analytic system QA was not available for evaluation. 2. The laboratory director confirmed on June 11, 2026 at 1:02 PM, that the laboratory QA pre-analytic system activities records were not available in the laboratory, and that the laboratory failed to monitor the pre-analytic laboratory systems related to: patient test requests, specimen submission, handling and referral, since January 2025.
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. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) activities records (years 2025-2026) and interview with the laboratory director on June 11, 2026 at 12:55 PM, the laboratory failed to evaluate and monitor the analytic laboratory systems related to: test procedures; test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability; specimen and reagent storage condition; equipment or test maintenance and function checks; establishment and verification of method performance specifications; calibration, and calibration verification; control procedures; comparison of test results; corrective actions; and patient test records, since January 2025. The findings include: 1. On June 11, 2026 at 12:55 PM, the laboratory analytic system QA 2025-2026 records were requested. The analytic system QA was not available for evaluation. 2. The laboratory director confirmed on June 11, 2026 at 1:02 PM, that the laboratory QA analytic system activities records were not available in the laboratory, and that the laboratory failed to monitor the analytic laboratory systems related to: test procedures; test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability; specimen and reagent storage condition; equipment or test maintenance and function checks; establishment and verification of method performance specifications; calibration, and calibration verification; control procedures; comparison of test results; corrective actions; and patient test records, since January 2025.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 lack of Quality Assessment (QA) activities records (years 2025-2026) and interview with the laboratory director on June 11, 2026 at 12:55 PM, the laboratory failed to evaluate and monitor the post-analytic laboratory systems related to: patient test reports, turn around time, and procedures for notification of test results, and downtime procedures, since January 2025. The findings include: 1. On June 11, 2026 at 12:55 PM, the laboratory post-analytic system QA 2025-2026 records were requested. The post-analytic system QA was not available for evaluation. 2. The laboratory director confirmed on June 11, 2026 at 1:02 PM, that the laboratory QA post-analytic system activities records were not available in the laboratory, and that the laboratory failed to monitor the post-analytic laboratory systems related to: patient test reports, turn around time, and procedures for notification of test results, and downtime procedures, since January 2025.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 lack of Quality Assessment (QA) activities records (years 2025-2026) and interview with the laboratory director on June 11, 2026 at 1:02 PM, the laboratory director failed to ensure compliance with the quality assessment program. Refer to D5291, D5391, D5791, and D5891.