Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658099	10/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Guaynabo	Herminio Diaz Navarro # 26, Guaynabo, 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 Guaynabo on October 3, 2025. 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 October 3, 2025.
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 2024-2025) and interview with the laboratory technical supervisor on October 3, 2025 at 12:10 PM; it was determined that the laboratory failed to evaluate and monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications, and personnel competency since January 2024. The findings include: 1. On October 3, 2025 at 12:10 PM the laboratory general system QA 2024-2025 records were requested. The general system QA was not available for evaluation. 2. The laboratory technical supervisor confirmed on October 3, 2025 at 12:15 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 since January 2024.
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 2024-2025) and interview with the laboratory technical supervisor on October 3, 2025 at 12:10 PM; it was determined that the laboratory failed to evaluate and monitor the pre-analytic laboratory systems related to: patient test requests and specimen submission, handling and referral, since January 2024. The findings include: 1. On October 3, 2025 at 12:10 PM the laboratory pre-analytic system QA 2024-2025 records were requested. The pre-analytic system QA was not available for evaluation. 2. The laboratory technical supervisor confirmed on October 3, 2025 at 12:15 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 and specimen submission, handling and referral, since January 2024.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: A. Based on human chorionic gonadotropin (hCG) test quality control records review (year 2024 -2025) and laboratory technical supervisor interview on October 3, 2025, at 10:22 AM, it was determined that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use, on August 1, 2025. The findings include: 1. The laboratory performed hCG test by Instant View Pregnancy Test method. 2. The hCG quality control test records reviewed (years 2024-2025) on October 3, 2025, at 10:22 AM, and showed that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity, lot 088710 Expiration date 7/31/26, prior to placing it in routine use on August 1, 2025. 3. The laboratory performed and reported 6 out of 6 hCG patient samples. (Reviewed on October 3, 2025, at 10:22 AM.) 4. The laboratory technical supervisor confirmed on October 3, 2025, at 10:28 AM, that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use. B. Based on urinalysis quality control records review (years 2024-2025) and laboratory technical supervisor interview on October 3, 2025 at 11:09 AM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials (normal and abnormal controls), when the laboratory processed and reported 506 patient urinalysis samples from April 1, 2025 to October 3, 2025. The

	findings include: 1. The laboratory performs urinalysis tests with the Clinitek 100 instrument. 2. The urinalysis quality control records reviewed (years 2024-2025) on October 3, 2025 at 11:09 AM, from April 1, 2025 to October 3, 2025, showed that there was no evaluation of the manufacturer's stated values for the normal control material lot number 330328 Expiration date 11/30/2025, and abnormal control material lot number 330329 Expiration date 11/30/2025, prior to placing them in routine use on April 1, 2025. 3. The laboratory technical supervisor confirmed on October 3, 2025 at 11:14 AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for urinalysis tests performed by the Clinitek 100 instrument, when they processed and reported 506 patient samples from April 1, 2025 to October 3, 2025. C. Based on Rapid Reagin Plasma (RPR) quality control records review (years 2024-2025) and laboratory technical supervisor interview on October 3, 2025 at 11:46 AM, it was determined that the laboratory failed to evaluate the reactivity of the new lot of RPR reagent prior to placing it in routine use on July 1, 2025, when the laboratory processed and reported 2,171 RPR patient samples from July 1, 2025 to October 3, 2025. The findings include: 1. The laboratory performs RPR tests with the ASI RPR Card Test For Syphilis reagent kit. 2. The RPR quality control records reviewed (years 2024-2025) on October 3, 2025 at 11:46 AM, from July 1, 2025 to October 3, 2025, showed that there was no evaluation of the reactivity of the RPR reagent, lot number 5E12R6, prior to placing it in routine use on July 1, 2025. 3. The laboratory technical supervisor confirmed on October 3, 2025 at 11:55 AM, that the laboratory failed to evaluate the reactivity of the new lot of RPR reagent prior to placing it in routine use, when they processed and reported 2,171 RPR patient samples from July 1, 2025 to October 3, 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 2024-2025) and interview with the laboratory technical supervisor on October 3, 2025 at 12:10 PM; it was determined that the laboratory failed to evaluate and monitor the analytic laboratory systems related to: comparison of test results and patient test records, since January 2024. The findings include: 1. On October 3, 2025 at 12:10 PM the laboratory analytic system QA 2024-2025 records were requested. The analytic system QA was not available for evaluation. 2. The laboratory technical supervisor confirmed on October 3, 2025 at 12:15 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: comparison of test results and patient test records, since January 2024.
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 2024-2025) and interview with the laboratory technical supervisor on October 3, 2025 at 12:10 PM; it was determined that the laboratory failed to evaluate and monitor the post-analytic laboratory systems related to: patient test reports and turn around time, since January 2024. The findings include: 1. On October 3, 2025 at 12:10 PM the laboratory post-analytic system QA 2024-2025 records were requested. The post-analytic system QA was not available for evaluation. 2. The laboratory technical supervisor confirmed on October 3, 2025 at 12:15 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 and turn around time, since January 2024.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of Human chorionic gonadotropin (hCG), Rapid Reagin Plasma (RPR), and urinalysis quality control records (years 2024-2025), and interview with the laboratory technical supervisor on October 3, 2025 at 11:55 AM; it was determined that the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the hCG, RPR, and urinalysis quality control requirements. Refer to D5469.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 the Quality Assessment (QA) records review (years 2024-2025), and laboratory technical supervisor interview on October 3, 2025 at 12:15 PM, it was determined that the laboratory director failed to ensure compliance with QA requirements. Refer to D5291, D5391, D5791, and D5891.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (b)(4) 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 review of Human chorionic gonadotropin (hCG), Rapid Reagin Plasma (RPR), and urinalysis quality control records (years 2024-2025), and interview with the laboratory technical supervisor on October 3, 2025 at 12:15 PM; it was determined that the laboratory technical supervisor did not ensure that the quality control requirements were followed. Refer to D5469.