Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658026	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Bayamon	Edif Estacionamiento Joaquin Montesino, Bayamon, 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 Bayamon on May 14, 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 May 14, 2025.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on manufacturer's specifications, hematology preventive maintenance records review (years 2024 - 2025) and laboratory director interview on May 14, 2025 at 11: 30 AM, it was determined that the laboratory failed to perform and document the preventive maintenance as required by the manufacturer of the Cell Dyn 3200 hematology instrument, when they processed and reported 246 Complete Blood Count (CBC) tests from January 1, 2024 to February 29, 2024. The findings include: 1. The laboratory uses Cell Dyn 3200 hematology instrument to perform CBC patient tests. 2. The manufacturer's specifications establishes that the monthly maintenance of the Cell Dyn 3200 hematology instrument are the following: clean fan filter, run extended auto clean and replace diluent/sheath filter. 3. On May 14, 2025 at 11:25 AM, review of preventive maintenance records from January 1, 2024 to February 29, 2024, showed that the laboratory did not perform nor document the monthly preventive maintenance of the hematology instrument. 4. The laboratory processed and reported 246 CBC tests from January 1, 2024 to February 29, 2024. 5. The laboratory director

	confirmed on May 14, 2025, at 11:30 AM, that the laboratory failed to follow the manufacturer's specifications for the preventive maintenance of the Cell Dyn 3200 hematology instrument.
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 urinalysis quality control records review (years 2024 - 2025) and laboratory director interview on May 14, 2025 at 12:19 PM, 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 137 patient urinalysis samples from April 1, 2024 to July 1, 2024. The findings include: 1. The laboratory performs urinalysis tests with the AimStrip Urine Analyzer 2 instrument and uses Thermo Scientific MAS UA control material. 2. The urinalysis quality control records reviewed (years 2024 - 2025) on May 14, 2025 at 12:19 PM, from April 1, 2024 to July 1, 2024, showed that there was no evaluation of the manufacturer's stated values for the normal control lot number 326201 and abnormal control lot number 326202 prior to placing them in routine use on April 1, 2024. 3. The laboratory director confirmed on May 14, 2025 at 12:24 PM, that the laboratory failed to evaluate the stated value of the new lot of control materials prior to placing them in routine use for urinalysis tests, performed by the AimStrip Urine Analyzer 2 instrument, when they processed and reported 137 patient samples from April 1, 2024 to July 1, 2024. B. Based on Rapid Reagin Plasma (RPR) quality control records review (years 2024 - 2025) and laboratory director interview on May 14, 2025 at 12:51 PM, 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, when the laboratory processed and reported 51 RPR patient samples from December 4, 2024 to April 23, 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 May 14, 2025 at 12:51 PM, from December 4, 2024 to April 23, 2025, showed that there was no evaluation of the reactivity of the RPR reagent, lot number CA3E26RH, prior to placing it in routine use on December 4, 2024. 3. The laboratory director confirmed on May 14, 2025 at 12:55 PM, 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 51 RPR patient samples from December 4, 2024 to April 23, 2025.
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 hematology instrument monthly maintenance quality control records, syphilis serology Rapid Reagin Plasma (RPR) quality control records, and urinalysis quality control records and interview with the laboratory director on May 14, 2025 at 1:10 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5429 and D5469.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) (b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: Based on hematology instrument monthly maintenance quality control records, syphilis serology Rapid Reagin Plasma (RPR) quality control records, and urinalysis quality control records and interview with the laboratory director and testing personnel on May 14, 2025 at 1:10 PM, it was determined that the laboratory testing personnel failed to follow the manufacturer's instructions and quality control procedures for hematology, syphilis serology, and urinalysis tests. Refer to D5429 and D5469.