Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0689663	11/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Bayamon	Calle Parque Esq Rossi Local 4, 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 the Laboratorio Clnico Bayamon on November 17, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on November 17, 2025.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of routine chemistry and endocrinology calibration verification records review (years 2024 - 2025) and laboratory director interview on November 17, 2025, at 10:46 AM , it was found that the laboratory did not perform , at least every 6

	months, the calibration verification procedures for the following routine chemistry and endocrinology tests: carcinoembryonic Antigen (CEA), follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (Prol), thyroxine binding globulin uptake (T3 uptake), Vitamin B-12, Vitamin D by the Vitros 7600 Chemistry and Endocrinology analyzer. The laboratory processed and reported 6,862 out of 6,862 patient samples from February 2025 to November 2025. The findings include: 1. The laboratory validated the Vitros 7600 analyzer on January 21, 2025 and began to perform routine chemistry and endocrinology tests on February 2025. (Review on November 17, 2025 at 10:21 AM). 2. During interview with the laboratory director the calibration verification were requested on November 17, 2025 at 10:40 AM. The calibration verification were not performed for the following analytes: carcinoembryonic Antigen (CEA), follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (Prol), thyroxine binding globulin uptake (T3 uptake), Vitamin B-12, Vitamin D. 3. The laboratory director stated on November 17, 2025, at 10:46 AM, that the calibration verification was not carried us during the year 2025. 4. The laboratory processed and reported 6,862 out of 6,862 patient samples from February 2025 to November 2025 for the following routine chemistry and endocrinology tests: carcinoembryonic Antigen (CEA), follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (Prol), thyroxine binding globulin uptake (T3 uptake), Vitamin B-12, Vitamin D by the Vitros 7600 Chemistry and Endocrinology analyzer.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) (b)(3) Adhere to the laboratory's 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 lack of routine chemistry and endocrinology calibration verification records review (years 2024 - 2025) and laboratory director interview on November 17, 2025, at 10:46 AM , it was found that the laboratory testing personnel failed to perform the calibration verification at least every 6 months for the following routine chemistry and endocrinology tests: carcinoembryonic Antigen (CEA), follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (Prol), thyroxine binding globulin uptake (T3 uptake), Vitamin B-12, Vitamin D by the Vitros 7600 Chemistry and Endocrinology analyzer. The laboratory processed and reported 6,862 out of 6,862 patient samples from February 2025 to November 2025. Refer to D5439.
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 routine chemistry and endocrinology calibration verification records review (years 2024 - 2025) and laboratory director interview on November 17, 2025, at 10:46 AM , it was found that the laboratory director failed to ensure that the calibration verification were performed at least every 6 months for the following

	routine chemistry and endocrinology tests: carcinoembryonic Antigen (CEA), follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (Prol), thyroxine binding globulin uptake (T3 uptake), Vitamin B-12, Vitamin D by the Vitros 7600 Chemistry and Endocrinology analyzer. The laboratory processed and reported 6,862 out of 6,862 patient samples from February 2025 to November 2025. Refer to D5439.