Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1097944	01/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Beatriz Inc	Car Pr-787 Km 4 Hm 7 Barrio Bayamon, Cidra, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on laboratory procedures manual, laboratory quality control records review and laboratory supervisor interview on January 18, 2024 at 11:13 AM, it was determined that the laboratory failed to monitor and document the laboratory's voltage, refrigerator and freezer temperatures and the preventive maintenance of the eye wash station. The findings include: 1. The laboratory procedures manual was reviewed on January 18, 2024 at 11:00 AM; and showed that the laboratory has established that the laboratory monitor and document the voltage, refrigerator and freezer temperature and the preventive maintenance of the eye wash station must be daily. 2. The quality control record showed that since December 2022, the laboratory did not monitor and document the daily the voltage, refrigerator and freezer temperatures and the preventive maintenance of the eye wash station. 4. The laboratory supervisor confirmed on January 18, 2024 at 11:13 AM, that the laboratory did not monitor and document the voltage, refrigerator and freezer temperatures, and the preventive maintenance of the eye wash station since December 2022.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on laboratory procedures manual, laboratory quality control records review and laboratory supervisor interview on January 18, 2024 at 11:13 AM, it was determined that the laboratory failed to monitor and document the laboratory maintenance of rotator, centrifuge maintenance, microscope maintenance since December 2022. The findings include: 1. The laboratory procedures manual was reviewed on January 18, 2024 at 11:00 AM; and established that the laboratory must monitor and document, every day, the rotator maintenance, centrifuge maintenance, microscope maintenance. 2. The quality control showed that since December 2022 the laboratory did not monitor and document the daily rotator maintenance, centrifuge maintenance, microscope maintenance. 4. The laboratory supervisor confirmed on January 18, 2024 at 11:13 AM, that the laboratory did not monitor and document the rotator maintenance, centrifuge maintenance and microscope maintenance since December 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 hematology calibration records reviewed and laboratory supervisor interview on January 18, 2024 at 10:26 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency

	recommended by the manufacturer's instructions (semi-annually) for the hematology tests performed by the Sysmex XN-350 hematology system. The laboratory did not performed the calibration verification procedures scheduled for December 2022, June 2023 neither December 2023. The findings include: 1. The laboratory uses a Sysmex XN-350 hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that the laboratory must perform the calibration verification procedures semi-annually. 3. On January 18, 2024 at 10:00 AM, the calibration records of XN-350 hematology system showed that the laboratory did not perform at least semi-annually the calibration verification procedures. The last calibration verification procedures were done on June 2022. 4. The laboratory supervisor confirmed on January 18, 2024 at 10:26 AM, that the laboratory did not perform at least semi-annually the calibration verification procedures for the XN-350 hematology system. The laboratory processed and reported 1,732 CBC patient's samples from June 2023 to December 2023.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records and laboratory supervisor interview on January 18, 2024 at 9:35 AM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for analytic systems. The findings include: 1. On January 18, 2024 at 9:30 AM, the laboratory QA record was requested and showed that the specimen and reagent storage conditions must be performed twice a year. 2. Since January 2023 the laboratory did not evaluate practices related to: specimen and reagent storage conditions. 3. The laboratory supervisor confirmed on January 18, 2024 at 9:35 AM, that the laboratory did not evaluate the specimen and reagent storage conditions since January 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 review and laboratory supervisor interview on January 18, 2024 at 9:42 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: accuracy of calculated data and results sent to interfaced systems. The findings include: 1. The Quality Assessment records was reviewed on January 18, 2024 at 9:30AM, and showed that the evaluations of the laboratory calculated data for hematology and chemistry, and the results sent to interfaced systems must be performed twice a year. 2. The laboratory did not evaluate the accuracy of calculated data and the results sent to interfaced

	system since December 2022. 3. The laboratory supervisor confirmed on January 18, 2024 at 9:42 AM, that the laboratory did not evaluate the accuracy of calculated data and the results sent to interfaced system since December 2022.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 the quality control records review (year 2023 and 2024), and interview with the laboratory supervisor on January 18, 2024 at 11:30 AM; it was determined that the laboratory director failed to ensure that the quality control program were follow. Refer to D5413, D5435 and D5437.
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 January 18, 2024 at 11:30 AM; it was determined that the laboratory director failed to ensure the compliance with QA requirements year 2023. Refer to D5791 and D5891.