Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0912552	10/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Baco Statlab Ii	Carr 2, Km 149 Hm 5, Bo Sabanetas Suite Num 15, Mayaguez, 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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program scores review (2023-2024) and laboratory director interview on October 25, 2024 at 9:00 A..M., it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results for white blood cell count (WBC) and platelets. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed since February 2023. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in white blood cell count (WBC) and platelets test in the first testing event performed in March 2024. No remedial actions were taken. 3. The laboratory director confirmed on October 25, 2024 at 90:10 A.M. , that the laboratory failed to take remedial actions when obtained unsatisfactory results of 60 percent in white blood cell count (WBC) and platelets test in the first testing event performed in March 2024.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing records (2023-2024) and laboratory director interview on October 25, 2024 at 8:45 A.M., it was determined that the laboratory failed to retain proficiency testing results for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed from February 2023 to August 2024. 2. The laboratory did not have available the proficiency testing results since 2023. 3. The laboratory director confirmed on October 25, 2024 at 9:50 A.M. , that the laboratory did not have available the Proficiency Testing results since February 2023.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on Quality Assessment records (2023-2024) and laboratory director interview on October 25, 2024, it was determined that the laboratory failed to have written procedures to ensure confidentiality of patient information. The findings include: 1. The written procedures reviewed on October 25, 2024 at 10:10 A.M. did not include any reference how the laboratory ensure the patient confidentiality. 2. The laboratory director confirmed on October 25, 2024 at 10:30 AM., that the laboratory did have written procedures to ensure patient confidentiality.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of laboratory written procedures (2023-2024) and interview with the laboratory director on October 25, 2024 at 10:10 A.M.. it was determined that the laboratory did not have any written protocol for complaint investigations. The findings include: 1. The written procedures reviewed on October 25, 2024 at 10:10 A. M. did not include any reference how the laboratory will evaluate the complaint investigations. 2. The laboratory director confirmed on October 25, 2024 at 10:30 AM., that the laboratory did not have written procedures to document and evaluate any complaint investigations.
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 2023-2024) and laboratory director interview on October 25, 2024 at 12:00 PM, it was determined that the laboratory failed to establish written protocols to evaluate and monitor the following: patient confidentiality and complaint investigation in the general laboratory system since January 2023. Refer to D5201, D5205. The findings include: 1. During interview with the LD, the QA written protocols were requested. 2. The LD director stated on October 25, 2024 at 11:30 A.M. that no QA written protocols were available.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration verification records (year 2023-2024) and laboratory director interview on October 25, 2024 at 9:50 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency established by the laboratory (every six months) for the hematology tests performed by the Mindray hematology system. The findings include: 1. The laboratory uses a Myndray hematology system for CBC (Complete blood count) patient's tests. 2. The laboratory established to perform calibration verification procedures, each 6 months. 3. On October 25, 2024 at 9:50 AM, the calibration records of the hematology system showed that the laboratory did not perform at least every 6 months the calibration verification procedures. The last calibration verification procedures were done on March 30, 2023. 4. The laboratory processed and reported 3,508 CBC patient's samples from March 1, 2023 to October 2024. 5. The laboratory director confirmed on October 25, 2024 at 10:30 A.M., that the laboratory did not perform at least every 6 months the calibration verification procedures for the Myndray hematology system since March 30, 2023.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on endocrinology quality control records review (year 2023-2024) and interview with the laboratory testing personnel on October 25, 2024 10:35 A.M. , it was determined that the laboratory failed to include a negative and positive control material when performed hCG test. The findings include : 1. The laboratory performed hCG (human chorionic gonadotropin) by Alere one step method. 2. Endocrinology quality control logs were reviewed from January 2024 to October 25, 2024 (review on October 25, 2024 at 10:35 A.M.) 3. The records showed that the laboratory did not include each day of testing a negative and positive control material from February 12, 2024 to October 12, 2024. 4. The laboratory performed and reported 39 patient samples those days. 5. The laboratory testing personnel stated during the survey on October 25, 2024 at 10:45 a.m. that the laboratory run a negative and positive control material when opened a new lot or box of hCG test. 6. The laboratory director confirmed on October 25, 2024 at 10:45 a.m. , that the laboratory failed to include a negative and positive control material each day of testing when performed hCG test.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on Proficiency testing records review (2023-2024) and laboratory director interview on Octuber 25, 2024 at 11:15 P.M., it was determined that the laboratory director did not fulfill her responsibilities to ensure that the laboratory failed to take remedial actions when obtained unsatisfactory results of 60 percent in WBC and platelets tests in March 2024. Refer D 2128.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on hematology calibration records , hCG quality control records review (2023-2024) and interview with the laboratory director on October 25, 2024 at 12:00 P.M., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5437 and D5449.

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Quality Assessment records review (year 2023-2024) and laboratory director interview on October 25, 2024 at 12:00 P.M.it was determined that laboratory director failed to ensure compliance with quality assessment requirements. Refer to D 5291.