Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1093514	03/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Bahia	Ave Ponce De Leon # 125 Bo Amelia, 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 Bahia on March 6, 2026. 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 March 6, 2026.
D2067	SYPHILIS SEROLOGY CFR(s): 493.835(b) (b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), CASPER Report 0155D, proficiency testing (PT) records, and telephone interview with the laboratory director on March 6, 2026, at 10:55 a.m., the laboratory failed to participate in the first proficiency testing (PT) event for syphilis serology. The laboratory processed and reported 212 out of 212 syphilis serology patient tests between December 2023 to September 2024. Findings include: 1. On March 6, 2026, at 10:55 a.m., the Puerto Rico Proficiency Testing Service Program (PRPTSP) scores and CASPER Report 0155D were reviewed. The review showed that the laboratory received a score of 0% for the first Diagnostic

	Immunology testing event for syphilis serology. 2. On March 6, 2026, at 10:58 a.m., review of the proficiency testing (PT) records showed that the laboratory did not participate in or submitted results for the first proficiency testing event for syphilis serology. 3. The laboratory processed and reported 212 out 212 syphilis serology patient tests between December 2023 to September 2024. 4. During a telephone interview on March 6, 2026, at 11:08 a.m., the laboratory director stated that the PT samples for the first syphilis serology testing event were not received or processed in the laboratory.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on the Quality Assessment (QA) records review (year 2025) and interview with the laboratory owner on March 6, 2026, at 12:00 p.m., the laboratory failed to follow the established QA program for evaluating and documenting communication problems for the period of July through December 2025. The findings include: 1. On March 6, 2026, at 12:00 p.m., the QA records were reviewed and showed that the QA program for communications problems must be evaluated monthly. The records showed that the last communication evaluation was performed on June 30, 2025. 2. During interview on March 6, 2026, at 12:05 p.m., the laboratory personnel confirmed that the laboratory did not perform communication evaluations from July through December 2025.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, refrigerator temperature records review (years 2025 - 2026), ImmunoCard Mycoplasma manufacturer's instructions, and laboratory personnel interview on March 6, 2026, at 12:30 p.m., the laboratory failed to follow the manufacturer's instruction regarding the required storage temperature conditions when 64 out of 64 patient specimens were processed and reported from August 12, 2025, through December 29,2025. The findings include: 1. On March 6, 2026, at 12:30 p.m., observation of refrigerator #2 used for reagent storage showed ImmunoCard Mycoplasma test kits stored in the refrigerator. The laboratory established that refrigerator storage temperatures for these reagents must be maintained between 2C and 8C. 2. The refrigerator temperature monitoring records were reviewed from January 2, 2025, through March 5, 2026. Review of the records showed that the laboratory did not monitor or document the storage temperature for refrigerator #2 during this period. 3. On March 6, 2026, at 12:35 p.m., the ImmunoCard Mycoplasma manufacturer's instructions were reviewed. The manufacturer's instructions stated that

	the test kit must be stored at 2C to 8C and returned promptly to the refrigerator after each use. 4. The laboratory processed and reported 64 out of 64 Mycoplasma patient tests from August 12, 2025, through December 29, 2025. 5. During interview on March 6, 2026, at 12:45 p.m., laboratory personnel confirmed that patient specimens were processed and reported while the laboratory did not document or monitor the storage temperature of refrigerator #2 during that period.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation of the laboratory specimen collection area, the patient census report review, and interview with the laboratory personnel on March 6, 2026, at 9:20 a.m., the laboratory used sample collection tubes that have exceeded their expiration date. The laboratory collected and referred 78 out of 78 patient specimens using expired specimen collection tubes from October 1,2025 to March 5, 2026. The findings include: 1. On March 6, 2026, at 9:22 a.m., direct observation of the laboratory specimen collection area showed eleven (11) Buffered Sodium Citrate (pale blue top) specimen collection tubes, lot number 4344930, with an expiration date of September 30, 2025. 2. The patient census report review showed that 78 coagulation specimens were collected and referred for testing between October 1,2025 to March 5, 2026, including: - 38 specimens for Partial Thromboplastin Time (PTT) - 33 specimens for Prothrombin Time (PT) 3. During interview on March 6, 2026, at 9: 25 a.m., the laboratory personnel confirmed that the coagulation specimens (PT and PTT) were collected using the expired Buffered Sodium Citrate specimen collection tubes.
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 review of the Quality Assessment (QA) records (year 2025) and interview with the laboratory owner on March 6, 2026, at 12:18 p.m., the laboratory failed to follow the established QA program for semiannual turnaround time (TAT) evaluations during year 2025. Findings include: 1. On March 6, 2026, at 12:18 p.m., the QA records were reviewed and showed that the QA program for evaluate TAT must be every six months. 2. The QA records showed that the laboratory performed the first semiannual TAT evaluation on March 15, 2025, and do not perform the second semiannual TAT evaluation in September 2025. 3. During interview on March 6, 2026, at 12:30 p.m., the laboratory owner confirmed that the laboratory did not perform TAT evaluations every six months.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024 - 2025) and laboratory personnel interview on March 6, 2026, at 2: 00 p.m. the laboratory director failed to evaluate any problems related to proficiency testing (PT) performance. Refer to D2067.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 review of the Quality Control (QC) records (year 2025), the Quality Assessment (QA) program (years 2024-2025), and interview with the laboratory personnel on March 6, 2026, at 2:00 p.m., the laboratory director failed to fulfill his responsibilities to ensure compliance with the laboratory's quality control and quality assessment requirements. Refer to D5207, D5411, D5417, and D5891.