Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0982567	05/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Y Bacteriologico Licer	216 Calle Munoz Rivera Plaza Buxo Suite #2, San Lorenzo, 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 Y Bacteriologico Licer on May 7, 2026. 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 7, 2026.
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 observation, quality control records review, and laboratory director interview on May 7, 2026 at 9:38 AM, the laboratory used the wright stain reagent kit with exceeded expiration date, on 38 peripheral smear patient tests from July 7, 2024 to May 7, 2026. The findings include: 1. The laboratory uses Camco Quik Stain II Wright- giemsa stain reagent kit to perform hematology peripheral smear tests. 2. Observation of the laboratory wright stain reagent kit on May 7, 2026 at 9:38 AM, showed that wright stain reagent in use exceeded the expiration date, lot # 1029, expiration date July 6, 2024. 3. Wright stain hematology quality control records review on May 7, 2026 at 9:38 AM, showed that the laboratory used the wright stain reagent kit with exceeded expiration date, when the laboratory processed and reported 38 peripheral smear patient tests from July 7, 2024 to May 7, 2026. 4. The laboratory director confirmed on May 7, 2026 at 9:45 AM, that the laboratory used wright stain reagent kit with exceeded expiration, when the laboratory processed and reported 38 peripheral smear patient tests from July 7, 2024 to May, 7, 2026.

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 lack of Cobas e411 maintenance quality control records, manufacturer's instructions, and laboratory director interview on May 7, 2026 at 2:32 PM, the laboratory failed to perform the following instrument maintenance: daily, weekly, every two weeks and as needed instrument maintenance, when they processed and reported 10, 876 patient samples from January 1, 2025 to May 7, 2026 for special chemistry tests. The findings include: 1. The laboratory uses the Cobas e411 instrument to perform special chemistry tests. 2. Review of the Cobas e411 instrument manufacturer's instructions on May 7, 2026 at 2:26 PM, showed that the instrument maintenance includes the following: daily: clean sample reagent probe, check condensation inside compartments, check water level, empty liquid and solid waste, weekly: clean sipper probe, and incubator and aspiration station, every two weeks: clean rinse station, perform liquid flow cleaning, as needed: perform finalization maintenance, clean: system water container, liquid waste container, microbead mixer, ProCell & CleanCell compartments, reagent rotor & compartments, reagent compartment, and perform empty solid waste tray and protect the measuring cell. 3. On May 7, 2026 at 2:32 PM, the Cobas e411 instrument maintenance quality control records were requested. The laboratory did not have instrument maintenance records since January 1, 2025 to May 7, 2026, when they processed and reported 10, 876 patient specimens for special chemistry tests. 4. The laboratory director confirmed on May 7, 2026 at 2:39 PM, that the laboratory did not perform the instrument maintenance of the special chemistry instrument from January 1, 2025 to May 7, 2026, when they processed and reported 10, 876 patient samples.
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, hematology wright stain quality control records review, and interview with the laboratory director on May 7, 2026 at 9:30 AM, the laboratory did not document the kit, lot and expiration date of the wright stain reagent. The findings include: 1. The laboratory uses Camco Quik Stain II Wright- giemsa stain reagent to perform hematology peripheral smear tests. 2. On May 7, 2026 at 9:30 AM, the hematology wright stain quality control records, showed that the laboratory did not document the following information: kit, lot and expiration date from July 7, 2024 to May 7, 2026, when they processed and reported 38 hematology peripheral smear patient's staining results. 3. The laboratory director confirmed at 9:35 AM that the laboratory failed to document the kit, lot and expiration date from the hematology stain kit that was in use from July 7, 2024 to May 7, 2026.

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 and chemistry observation, quality control records, manufacturer's instructions, and interview with the laboratory director on May 7, 2026 at 2:39 PM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the hematology and chemistry quality control requirements. Refer to D5417, D5429, and 5547.
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 and chemistry observation, quality control records, manufacturer's instructions, and interview with the laboratory director on May 7, 2026 at 2:39 PM, the laboratory testing personnel failed to perform and document all quality control activities to ensure compliance with the hematology and chemistry quality control requirements. Refer to D5417, D5429, and 5547.