Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0666367	11/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Perea Clinical Laboratory	Calle Dr Basora # 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clnico Hospital Perea on November 12, 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 12, 2025.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on coagulation standard operation manual (SOP), coagulation quality control records (years 2024-2025), control material inserts and interview with the laboratory general supervisor on November 12, 2025 at 1:20 PM, it was found that the acceptability criteria of the coagulation material based on the established results of an assayed material. The control material used by the laboratory was not evaluated for the instrument used by the facility. The findings include: 1. The laboratory performs Prothombin time (PT) and Partial Prothombin time (PTT) sample patient's test by ACL Elite Pro coagulation system. 2. Review of the coagulation standard operation manual (SOP), quality control records from January 2024 to October 2025, showed that the laboratory verified the control material acceptability criteria for lot # 100451821, in November 2025. 3. The manufacturer claimed a control range for PT level 1 between 10.0 - 13.0 seconds and PT level 2 between 17.0 - 23.0 seconds. 4. Review of the manufacturer's insert showed that the control material range was evaluated for the ACL Classic not the ACL Elite Pro. 5. The laboratory established a PT control range for level 2 of 24.97 - 31.74 seconds. 6. The general supervisor was

	interviewed on November 12, 2025 at 1:20 PM, about the laboratory procedure to state the control values, when material was defined to be used with an instrument different from the one used by the laboratory. The supervisor stated that they did evaluate the control material, however no procedure was established. 7. The laboratory processed and performed four hundred sixty-six (416) Prothombin time test (PT) sample test those days.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 Syphilis serology manufacturer's instructions, quality control records review (years 2024-2025) and interview with the laboratory general supervisor on November 12, 2025 at 1:20 PM, it was determined that the laboratory failed to perform RPR (rapid plasma reagin) test as required by manufacturer's instructions of the ASI RPR (rapid plasma reagin) method. The findings include: 1. The manufacturer's establishes that the RPR test must be performed at room temperature between 20 C to 30 C. Reviewed at 10:00 AM. 2. Review of syphillis serology quality control records from January 2024 to October 2025, showed that the laboratory processed and reported forty seven (47) RPR were patient's samples tests that were performed at temperatures below of the established range in the following eleven (11) days. Reviewed at 10:30 AM: Date Temp C samples 9/27/2024 19 C 2 11/29/2024 19 C 2 12/7/2024 19 C 1 1/9 /2025 19 C 7 1/13/2025 19 C 9 1/16/2025 19 C 2 1/25/2025 19 C 2 2/1/2025 19C 2 2/3 /2025 19 C 6 2/4/2025 19 C 5 2/5/2025 19 C 9 3. The laboratory general supervisor confirmed on November 12, 2025 at 1:20 PM, that the laboratory performed RPR (rapid plasma reagin) samples tests below the range estabilished by the manufacturer's those days.
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 the manufacturer's specifications, Preventive Maintenance (PM) records review (years 2023 - 2024), and the interview with the laboratory technical supervisor on November 12, 2025, at 10:30 AM, it was determined that the laboratory failed to perform the PM as required by the manufacturer of the BacT/Alert 3D system. The laboratory reported 4,984 out of 4,984 blood culture tests from December 29, 2024, to November 11, 2025. The findings include: 1. The laboratory used the BacT/Alert 3D system to perform blood culture testing. 2. The manufacturer's specifications stated

	that the "PMs are required to be performed annually". 3. The review of PM records showed that the laboratory did not perform the annual PM in the year 2024. The last PM was performed on December 28, 2023. 4. The laboratory reported 289 out of 4,984 positive blood cultures and 4,695 out of 4,984 negative blood cultures performed by the BacT/Alert 3D system from December 29, 2024, to November 11, 2025. 5. The laboratory technical supervisor confirmed on November 12, 2025, at 11: 11 AM, that the laboratory did not perform the annual PM of the BacT/Alert 3D system in the year 2024.
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 the Bacteriology preventive maintenance (PM) records (years 2023-2024), Coagulation standard operation manual (SOP), Coagulation quality control records (years 2024-2025), Rapid Plasma Reagin (RPR) quality control records (years 2024-2025), manufacturer's instructions, and interview with the laboratory technical supervisor on November 12, 2025 at 1:20 PM,it was determined that the laboratory director failed to ensure that the laboratory technical supervisor monitored compliance with the manufacturer's instructions (RPR and Bacteriology PM) and laboratory quality control requirements. Refer to D5401, D5413 and D5429.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the manufacturer's specifications, review of the Preventive Maintenance (PM) records for the Bact/Alert 3D System, and interview with the laboratory technical supervisor on November 11, 2025, at 1:20 PM, it was determined that the laboratory technical supervisor failed to verify and monitor that the required annual PM for the Bact/Alert 3D System was performed in the year 2024. Refer to D5429.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on Coagulation standard operation manual (SOP), Coagulation quality control

	records (years 2024-2025), control material inserts and syphilis serology (Rapid Plasma Reagin (RPR)) manufacturer's instructions, quality control records (years 2024-2025) and interview with the laboratory general supervisor on November 12, 2025 at 1:20 PM, it was determined that the laboratory general supervisor failed to fulfill his responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5401 and D5413.
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 Bacteriology Preventive Manintenance (PM) (years 2023-2024), manufacturer's instructions, syphilis serology quality control records review (years 2024-2025) and interview with the laboratory technical supervisor on November 12, 2025, at 1:20 PM; it was determined that the laboratory testing personnel failed to perform quality control activities to ensure compliance with the Rapid plasma reagin (RPR) quality control and annual PM for Bact/Alert 3D system requirements. Refer to D5413 and D5429.