Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658225	11/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Centro Medico Wilma N Vazquez	Carr Num 2 Km 39 Hm 5, Vega Baja, 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 Centro Medico Wilma N. Vazquez on November 18, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on November 18, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 Condition: Bacteriology 42 CFR 493.1441 Condition: Laboratory Director
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on bacteriology quality control records review (years 2024-2025) and interview with the laboratory director on November 18, 2025 at 3:00 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for bacteriology test. Refer to D5507.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials

	must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on the review of Erythrocyte Sedimentation Rate (ESR) quality control (QC) records (years 2024-2025) and the interview with the laboratory technical supervisor on November 18, 2025, at 11:15 AM, it was determined that the laboratory failed to verify the manufacturer's stated values of the ESR control materials prior to placing the lots into routine use. The laboratory processed and reported 606 out of 606 ESR patient samples from September 2, 2025, to November 18, 2025. The findings include: 1. The ESR quality control records showed that the laboratory used SEDiTROL Quality Controls (Levels 1 & 2) to monitor the precision of ESR testing on the miniiSED ESR Analyzer. 2. The QC records showed that the laboratory placed the following lots of ESR control materials into routine use without verifying the manufacturer's stated values: a. Control Lot: C146 (Level 1 Normal) / C246 (Level 2 Abnormal) Use dates: September 2, 2025, to November 3, 2025. Patient samples processed and reported: 477 b. Control Lot: C147 (Level 1 Normal) / C247 (Level 2 Abnormal) Use dates: November 4, 2025, to November 18, 2025. Patient samples processed and reported: 129 3. During the interview on November 18, 2025, at 12:00 PM, the laboratory technical supervisor acknowledged that the ESR control materials were placed into routine use without first verifying the manufacturer's stated values. 4. The laboratory processed and reported 606 ESR patient samples from September 2, 2025, to November 18, 2025.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on Bacteriology quality control records review (year 2024-2025) and laboratory general supervisor and director on November 18, 2025 at 9:10 A.M. , it was determined that the laboratory failed to verify the susceptibility quality control procedure, each day of use, when begin to use the new susceptibility panel. The findings include: 1. The laboratory use the Vitek 2 system to perform identification and susceptibility test. 2. The quality control records showed that the laboratory performed the validation procedure for AST(susceptibility testing) XN-808 on November 2024 and begin to use for patient samples on July 2025. The laboratory continued using the last AST panel GN-95 from November 2024 to June 2025. 3. The quality control records showed that laboratory performed the validation procedure for AST-XN-32 on December 2024 and begin to use for patient samples on August 2025. The laboratory continued using the last AST panel XN-09 from December 2024 to July 2025. 4. Records of records showed that the laboratory performed that the susceptibility quality control procedures weekly. 5. The laboratory performed 304

	patient samples for the panel XN-808 since July 1, 2025 to November 18, 2025 and 22 patient samples for the panel XN-32 since July 1, 2025 to November 18, 2025. 6. The laboratory general supervisor confirmed on November 18, 2025 at 1:00 P.M. that the laboratory failed to verify the susceptibility with microorganisms, each day of use.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on Bacteriology quality control records (year 2024-2025) and interview with the laboratory director on November 18, 2025 at 3:00 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.
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 quality control records review (year 2024-2025) and interview with the laboratory director on November 18, 2025 at 3:00 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the Hematology and Bacteriology quality control requirements. Refer to D6117.
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 Bacteriology and Hematology quality control records (year 2024-2025) and interview with the laboratory technical supervisor on November 18, 2025 at 3:00 PM, it was determined that the laboratory technical supervisor did not ensure that susceptibility quality control procedure were perform each day of testing and verify the manufacturer's stated values for Erythrocyte Sedimentation Rate (ESR) control materials before placing new lots into routine use. Refer to D5469 and D5507.