Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2164251	05/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Centro De Salud Familiar Menonita De Culebra	Calle William Font, Culebra, 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 announced CLIA Recertification survey at the Centro de Salud Familiar Menonita de Culebra on May 30, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the announced routine CLIA recertification survey ending on May 30, 2025.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration records, manufacturer's instructions, and laboratory director interview on May 30, 2025 at 11:35 AM, it was determined that the laboratory failed to perform the calibration procedures with at least the frequency

	recommended by the manufacturer's instructions (every six months) for the hematology tests performed by the DXH 520 hematology system. The laboratory processed and reported 139 patient's samples from April 2025 to May 2025. The findings include: 1. The laboratory uses a DXH 520 hematology system for CBC (Complete blood count) patient's tests. 2. Review of the manufacturer's instructions on May 30, 2025 at 11:35 AM, showed that the laboratory must perform the calibration procedures every six months. 3. On May 30, 2025 at 11:03 AM, the calibration records of DXH 520 hematology system showed that the laboratory did not perform at least every 6 months the calibration procedures. 4. The laboratory processed and reported 139 CBC patient's samples from April 10, 2025 to May 30, 2025. 5. The laboratory director confirmed on May 30, 2025 at 11:35 AM, that the laboratory did not perform at least every 6 months the calibration procedures for the DXH 520 hematology system. The laboratory processed and reported 139 patient's samples from April 2025 to May 2025.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on hematology calibration records, manufacturer's instructions, and laboratory director interview on May 30, 2025 at 11:35 AM, it was determined that the laboratory director (sole personnel) failed to ensure that the calibration procedures were performed with at least the frequency recommended by the manufacturer's instructions (every six months) for the hematology tests performed by the DXH 520 hematology system. The laboratory processed and reported 139 patient's samples from April 2025 to May 2025. Refer to D5439