Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658267	05/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Banco De Sangre De Servicios Mutuos	662 Ave Ponce De Leon Pda 37, San Juan, 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	An on-site CLIA Validation survey was completed by the Centers for Medicare & Medicaid Services (CMS), Survey Branch on May 22, 2025, with a standard level deficiency cited.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory automation room on May 22, 2025, a review of the laboratory quality control (QC) troubleshooting procedure, and an interview with the laboratory General Supervisor #1 (GS #1) on the Form CMS-209, the laboratory failed to document corrective actions taken to resolve failed QC testing on two of two Ortho Vision Swift instruments used for blood typing and antibody screening. Findings included: 1. Laboratory observation during a tour of the autormation room on May 22, 2025, at 8:53 AM, revealed two Ortho Vision Swift instruments were used for blood typing and antibody screening. Serial numbers 50004135 and 50004136. 2. An interview on May 22, 2025, at 9:56 AM with the GS #1, confirmed the laboratory did not document corrective actions taken to resolve the QC test failures, that occured approximately once per week, on the two Ortho Vision Swift instruments that resulted from the use of an expired patient blood sample

	reagent. 3. A review of the laboratory QC troubleshooting procedure, #W-601: Reagent Quality Control, page 5, Section 4.9, revealed, if the QC testing failed due to an expired reagent, the laboratory must document the corrective action taken that resolved the failure using the Form BSSM 659. 4. The annual test volume for blood typing and antibody screening was approximately 67,511.