Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658306	01/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Flores	Calle Marginal 12 Ave 65 Infanteria, 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	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Flores on January 23, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following condition and standard level deficiencies were found during the recertification CLIA survey ending on January 23, 2026.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the Mycoplasma pneumoniae IgM quality control records (year 2025-2026) on January 23, 2026 at 10:28 A.M., and laboratory testing personnel interview; it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae IgM test. Refer to D5449.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on the Mycoplasma pneumoniae IgM quality control records review, and testing personnel interview on January 23, 2026 at 10:28 AM, the laboratory failed to include an external negative and positive control material , each day of patient testing. The laboratory processed and reported 222 patient samples from June 30, 2025 to

	January 23, 2026. The findings include: 1. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. Review of the Mycoplasma pneumoniae IgM test quality control records on January 23, 2026 at 10: 28 AM, showed that the laboratory did not perform the external negative and positive control material each day of patient testing, when the laboratory processed and reported 222 patient samples from June 30, 2025 to January 23, 2026. 3. The laboratory testing personnel confirmed on January 23, 2026 at 10:33 AM, that the laboratory failed to perform the external negative and positive control material each day of patient testing. The laboratory processed and reported 222 patient samples from June 30, 2025 to January 23, 2026.
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 Mycoplasma Pneumoniae IgM quality control records (year 2025-2026) and interview with the laboratory testing personnel on January 23, 2026 at 10:35 AM, 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 Mycoplasma Pneumoniae IgM quality control records review, and interview with the laboratory testing personnel on January 23, 2026 at 10:33 AM, 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 D5449.