Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0679586	01/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Yesmar	Calle Colon #118, Aguada, 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 Yesmar on January 29, 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 29, 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 (August 2025 - January 2026) on January 29, 2026 at 10:00 A.M., and laboratory director interview; 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 laboratory director interview on January 29, 2026 at 10:00 AM, the laboratory failed to include an external negative and positive control material , each day of patient testing. The laboratory processed and reported 37 patient samples from September 8,

	2025 to January 28, 2026. The findings include: 1. The laboratory begin to uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests on August 15, 2025. 2. Review of the Mycoplasma pneumoniae IgM test quality control records on January 29, 2026 at 10:00 AM, showed that the laboratory did not include the external negative and positive control material, each day of patient testing, when the laboratory processed and reported 37 patient samples from September 8, 2025 to January 29, 2026. 3. The laboratory director confirmed on January 29, 2026 at 11:30 AM, that the laboratory failed to include an external negative and positive control material, each day of patient testing. The laboratory processed and reported 37 patient samples from September 8, 2025 to January 29, 2026.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on Mycoplasma Pneumoniae IgM quality control records (August 2025 - January 2026) and interview with the laboratory director on January 29, 2026 at 11:30 AM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. (see D6020).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 director on January 29, 2026 at 10:00 AM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. (see D5449).