

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2082435	(X3) Date Survey Completed 08/18/2026
Name of Provider or Supplier Laboratorio Clinico La 116	Street Address, City, State Centro Comercial Plaza Guanica, Bo Cano,, Guanica, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey at Laboratorio Clinico La 116 on August 18, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on August 18, 2026, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 General Immunology 42 CFR 493.1403 Laboratory Director
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 General Immunology (Mycoplasma) quality control records (years 2025-2026) and interview with the Laboratory Director (LD) on August 18, 2026, at 8:50 a.m., the laboratory failed to ensure compliance with the analytic system requirements for Mycoplasma testing. 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 review of the Mycoplasma pneumoniae quality control procedure, quality control records (years 2025-2026), patient testing records, and interview with the

laboratory director (LD) on August 18, 2026, at 8:50 a.m., the laboratory failed to include external negative and positive control materials each day of Mycoplasma pneumoniae patient testing. The laboratory performed and reported 598 out of 598 Mycoplasma pneumoniae patient specimens from January 4, 2025, through August 17, 2026. The findings included: 1. The laboratory performed qualitative Mycoplasma pneumoniae testing using the ImmunoCard Mycoplasma test system. 2. On August 18, 2026, at 8:50 a.m., the Mycoplasma quality control procedure was requested and reviewed. The procedure established that external positive and negative controls were processed with each new lot and each new shipment. 3. Review of the Mycoplasma pneumoniae quality control records showed that the laboratory did not include external negative and positive control materials each day of Mycoplasma pneumoniae patient testing. 4. Review of the patient testing records showed that the laboratory performed and reported 598 out of 598 Mycoplasma pneumoniae patient specimens from January 4, 2025, through August 17, 2026. 5. During interview on August 18, 2026, at 9:20 a.m., the laboratory director (LD) confirmed that the external negative and positive controls were not performed each day of Mycoplasma pneumoniae patient testing.

D5471

CONTROL PROCEDURES
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

This STANDARD is not met as evidenced by:
Based on review of the Mycoplasma pneumoniae quality control records (years 2025-2026), patient testing records, and interview with the laboratory director (LD) on August 18, 2026, at 9:05 a.m., the laboratory did not evaluate new lots of Mycoplasma pneumoniae test kits for positive and negative reactivity before placing them into routine use. The laboratory performed and reported 591 out of 591 Mycoplasma pneumoniae patient specimens from January 2, 2025, through August 17, 2026. The findings included: 1. The laboratory performed qualitative Mycoplasma pneumoniae testing using the ImmunoCard Mycoplasma test system. 2. Review of the Mycoplasma pneumoniae quality control and patient testing records showed that the laboratory did not evaluate the following new lots for positive and negative reactivity before placing them into routine use: a. ImmunoCard Mycoplasma - Lot 78651134 Expiration date: 2/14/2026 Used dates: 11/23/2024 through 1/8/2025 Patient specimens performed and reported: 7 b. ImmunoCard Mycoplasma - Lot 78651132 Expiration date: 01/01/2026 Used dates: 1/8/2025 through 2/14/2025 Patient specimens performed and reported: 84 c. ImmunoCard Mycoplasma - Lot 78651144 Expiration date: 5/13/2026 Used dates: 2/19/2025 through 4/8/2025 Patient specimens performed and reported: 91 d. ImmunoCard Mycoplasma - Lot 78651155 Expiration date: 8/12/2026 Used dates: 4/8/2025 through 4/26/2025 Patient specimens performed and reported: 23 e. ImmunoCard Mycoplasma - Lot 78651151 Expiration date: 8/12/2026 Used dates: 4/8/2025 through 9/3/2025 Patient specimens performed and reported: 136 f. ImmunoCard Mycoplasma - Lot 7865.1163 Expiration date: 10/23/2026 Used dates: 9/3/2025 through 1/16/2026 Patient specimens performed and reported: 109 g. ImmunoCard Mycoplasma - Lot 7865.1174 Expiration date: 2/5/2027

	Used dates: 1/16/2026 through 5/18/2026 Patient specimens performed and reported: 109 h. ImmunoCard Mycoplasma - Lot 7865.1183 Expiration date: 6/17/2027 Used dates: 5/23/2026 through 8/10/2026 Patient specimens performed and reported: 24 i. ImmunoCard Mycoplasma - Lot 7865.11835 Expiration date: 7/14/2027 Used dates: 8/10/2026 through 8/17/2026 Patient specimens performed and reported: 8 3. Review of the patient testing records showed that the laboratory performed and reported 591 out of 591 Mycoplasma pneumoniae patient specimens from January 2, 2025, through August 17, 2026. 4. During interview on August 18, 2026, at 9:20 a.m., the laboratory director (LD) confirmed that the new lots of Mycoplasma pneumoniae test kits were not evaluated for positive and negative reactivity before being placed into routine use.
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 review of Mycoplasma pneumoniae IgM quality control records, patient testing records, and interview with the laboratory director (LD) on August 18, 2026, at 12:30 p.m., the laboratory director failed to fulfill the responsibility to ensure that Mycoplasma pneumoniae IgM testing was performed in compliance with applicable quality control requirements. Refer to 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 review of Mycoplasma pneumoniae IgM quality control records, patient testing records, and interview with the laboratory director (LD) on August 18, 2026, at 12:30 p.m., the laboratory director failed to ensure compliance with quality control requirements for Mycoplasma pneumoniae IgM testing, including the performance of required external positive and negative controls each day of patient testing and the evaluation of new test kit lots before routine patient testing. Refer to D5449 and D5471.