Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0663075	07/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Las Lomas	1700 Ave J T Pinero Esq San Patricio, Rio Piedras, 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 Las Lomas on July 21, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on July 21, 2026.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of records and laboratory testing personnel interview on July 21, 2026 at 10:28 AM, it was determined that the laboratory did not evaluate that the performance specifications of the Alethia instrument for the Mycoplasma pneumoniae Direct assay, were affected or not after the relocalization of the instrument on the laboratory on July 13, 2026. The findings include: 1. On July 13, 2026 at 10:26 AM, the laboratory testing personnel stated that the Alethia instrument was relocated from the chemistry area to the hematology area of the laboratory. 2. During interview with the laboratory testing personnel on July 21, 2026 at 10:28 AM the evaluation of the established performance specifications was requested. The laboratory testing

	personnel stated that no verification was performed after the relocalization. 3. The laboratory processed and reported two (2) Mycoplasma pneumoniae Direct assay patient samples from July 13, 2026 to July 21, 2026.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: A. Based on the Mycoplasma pneumoniae IgM Individual Quality Control Plan (IQCP) reviewed and laboratory testing personnel interview on July 21, 2026 at 10:05 AM (years 2025-2026), it was determined that the laboratory did not perform ongoing monitoring of the effectiveness of their IQCP to perform the quality assesment (QA) evaluation, when the laboratory processed and reported one thousand nine hundred twenty two (1,922) Mycoplasma pneumoniae IgM (by Immunocard Meridian Bioscience Kit) patient samples from January 1, 2025 to July 21, 2026. The findings include: 1. During interview with the laboratory testing personnel on July 21, 2026 at 10:03 AM, the Mycoplasma pneumoniae IgM (by Immunocard Meridian Bioscience Kit) Individual Quality Control Plan (IQCP) evaluation was requested. Review of the approved IQCP documents showed that the laboratory implemented a reduced quality control frequency for Mycoplasma pneumoniae IgM since December 9, 2022. 2. Review of the Mycoplasma pneumoniae IgM IQCP documents on July 21, 2026 at 10: 05 AM, showed that the laboratory did not perform ongoing monitoring of the effectiveness of the IQCP to evaluate the QA (quality assesment) plan from January 1, 2025 to July 21, 2026. 3. The laboratory processed and reported 1,922 Mycoplasma pneumoniae IgM patient samples from January 1, 2025 to July 21, 2026, when the laboratory did not perform ongoing monitoring of the effectiveness of their IQCP to perform the quality assesment (QA) evaluation. B. Based on the Mycoplasma pneumoniae Direct Assay (by Alethia Instrument) Individual Quality Control Plan (IQCP) reviewed and laboratory testing personnel interview on July 21, 2026 at 10:16 AM, it was determined that the laboratory did not perform ongoing monitoring of the effectiveness of their IQCP to perform the quality assesment (QA) evaluation, when the laboratory processed and reported four hundred seventy three (473) Mycoplasma pneumoniae Direct Assay patient samples from December 21, 2023 to July 21, 2026. The findings include: 1. During interview with the laboratory testing personnel on July 21, 2026 at 10:13 AM, the Mycoplasma pneumoniae Direct Assay Individual Quality Control Plan (IQCP) evaluation was requested. Review of the approved IQCP documents showed that the laboratory implemented a reduced quality control frequency for Mycoplasma pneumoniae Direct Assay since December 21, 2023. 2. Review of the Mycoplasma pneumoniae Direct Assay (by Alethia Instrument) IQCP documents on July 21, 2026 at 10:16 AM, showed that the laboratory did not perform ongoing monitoring of the effectiveness of the IQCP to evaluate the QA (quality assesment) plan. 3. The laboratory processed and reported 473 Mycoplasma

	pneumoniae Direct Assay patient samples from December 21, 2023 to July 21, 2026, when the laboratory did not perform ongoing monitoring of the effectiveness of their IQCP to perform the quality assesment (QA) evaluation.
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 review of the quality assesment (QA) evaluation for the Mycoplasma pneumoniae Direct Assay Individual Quality Control Plan (IQCP) and laboratory testing personnel interview on July 21, 2026 at 10:16 AM, it was determined that the laboratory director failed to fulfill her duties and responsabilities to monitor and ensure compliance with the IQCP QA requirements. Refer to D5445.