Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2103412	07/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Neoclinico	Carr, Pr -2, Km 18, Hm 9, Comunidad Macun, Toa Baja, 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 Neoclnico on July 29, 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 29, 2026. .
D2026	BACTERIOLOGY CFR(s): 493.823(d) (d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalytsts Medical Laboratory Evaluation (AAB-MLE) proficiency laboratory records (2025-2026) and interview with the laboratory general supervisor on July 29, 2026 at 10:05 AM, the laboratory failed to take corrective action when obtained an unsatisfactory score in the bacteriology colony count in the third proficiency testing event of the year 2025. The finding includes: 1. The AAB-MLE proficiency records was reviewed on July 29, 2026 at 10:05 AM, and showed that the laboratory failed to take corrective action when obtained an unsatisfactory score in the bacteriology colony count third proficiency testing event of the year 2025. The laboratory obtained the following unsuccessful scores: bacteriology colony count: 50% 2. The laboratory general

	supervisor confirmed on July 29, 2026 at 10:20 A.M., that the laboratory failed to take corrective action when obtained an unsatisfactory score in the bacteriology colony count in the third proficiency testing event of the year 2025.
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 review of hematology performance specifications records and laboratory general director interview on July 29, 2026 at 11:15 A.M., the laboratory failed to complete the evaluation of the performance specifications of the new hematology system. The findings include: 1. The laboratory acquired on June 2025 a new system to perform hematology tests (Sysmex XS 1000). 2. The performance specifications records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 3. The laboratory general supervdirector confirmed on July 29, 2026 at 11:30A.M.. , that the laboratory did not verify if the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population prior to begin to test patient's samples. 4. The laboratory processed and reported approximately 1,949 hematology tests performed by Sysmex XS-1000 Pentra system since June 2025.
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: Based on the Mycoplasma pneumoniae IgM Individual Quality Control Plan (IQCP) reviewed and laboratory general supervisor interview on July 29, 2026 at 12:00 P.M (years 2025-2026), 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 255 Mycoplasma pneumoniae IgM (by Immunocard Meridian Bioscience Kit) patient samples from March 1, 2025 to July 29, 2026. The findings include: 1. During interview with the laboratory general supervisor on July 29, 2026 at 12:15 PM, 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 March 2025 2. Review of the Mycoplasma pneumoniae IgM IQCP documents on July 29, 2026 at 12:15 PM, showed that the laboratory did not perform ongoing monitoring of the effectiveness of the IQCP to evaluate the QA (quality assesment) plan from March 2025 to July 29, 2026. The laboratory processed and reported 255 Mycoplasma pneumoniae IgM patient samples from March 1, 2025 to July 29, 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 general supervisor interview on July 29, 2026 at 12:00 P. M, the laboratory director failed to fulfill her duties and responsabilities to monitor and ensure compliance with the IQCP QA requirements. Refer to D5445.