

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0669382	(X3) Date Survey Completed 07/09/2025
Name of Provider or Supplier Lab Clinico San Martin	Street Address, City, State 75 Dr Pedro Albizu Campos St, Lares, 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 San Martin on July 9, 2025. 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 9, 2025.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Syphilis serology Based on syphilis serology quality control records, manufacturer's instructions review, and laboratory supervisor interview, on July 9, 2025 at 10:10 AM, it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 1,489 patient specimens were processed and reported from January 1, 2024 to July 9, 2025. The findings include: 1. The laboratory uses the Aim RPR Test reagent kit to perform patient syphilis serology test. Review of the Aim RPR Test manufacturer's instructions on July 9, 2025 at 10:06 AM, showed that the laboratory must remove and wash the needle at the end of the day. 2. On July 9, 2025 at 10:10 AM the syphilis serology quality control records were reviewed. The records showed that the laboratory did not perform the needle wash as required by the manufacturer, when they processed and reported 1,489 patient specimens from January 1, 2024 to July 9, 2025. 3. The laboratory supervisor confirmed on July 9, 2025 at 10:15 AM, that the laboratory did not follow the manufacturer's instructions related to the needle wash, from January 1, 2024 to July 9, 2025. B. Coagulation Based on coagulation</p>

instrument Sysmex CA-500 maintenance records, and laboratory supervisor interview on July 9, 2025 at 10:27 AM, it was determined that the laboratory failed to perform the monthly maintenance of the instrument, when 1,104 patient specimens were processed and reported for coagulation tests from January 1, 2024 to July 9, 2025. The findings include: 1. The laboratory uses the Sysmex CA-500 instrument to perform patient's coagulation tests. 2. On July 9, 2025 at 10:27 AM, the Sysmex CA-500 instrument maintenance records were reviewed, and showed that the laboratory failed to perform the following monthly maintenance: Perform LED Calibration, when they processed and reported 1,104 patient specimens from January 1, 2024 to July 9, 2025. 3. The laboratory supervisor confirmed on July 9, 2025 at 10:33 AM, that the laboratory did not perform the monthly maintenance of the coagulation instrument.

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 the chemistry Atellica CI 1900 instrument performance verification results, and laboratory supervisor interview on July 9, 2025 at 11:19 AM, it was determined that the laboratory failed to evaluate the instrument's obtained results. The findings include: 1. On July 9, 2025 at 11:19 AM, review of the chemistry Atellica CI 1900 instrument performance verification results did not reflect the evaluation and signature of the laboratory director prior to begin to test chemistry patient samples. 2. On July 9, 2025 at 11:22 AM, laboratory supervisor stated that the chemistry Atellica CI 1900 instrument was used to perform patient testing since October 1, 2024. 3. The laboratory supervisor confirmed on July 9, 2025 at 11:24 AM that the laboratory director did not evaluate and sign the performance verification of the chemistry Atellica CI 1900 instrument. 4. The laboratory processed and reported 5,861 chemistry tests on the chemistry Atellica CI 1900 instrument from October 1, 2024 to July 9, 2025.

D6085

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)

(e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

This STANDARD is not met as evidenced by:
Based on review of the quality control records, manufacturer's instructions review, and interview with the laboratory supervisor on July 9, 2025 at 11:24 AM; it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5411, and D5421.