

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0669382	(X3) Date Survey Completed 08/02/2019
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on routine chemistry quality control records review (year 2018-2019) and laboratory director interview at 10:00 a.m. on August 2, 2019, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by the Dimension EXL 200 system. The findings include: 1. The laboratory uses since march 2017 a Dimension EXL 200 system for routine chemistry tests. 2. From January 2018 to</p>

August 2019, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by Dimension EXL 200 system. 3. The laboratory processed and reported 9,215 electrolytes patients specimens tests by the Dimension X pand system since January 2018. 4. The laboratory director confirmed on August 2, 2019 at 10:00 A.M., that the laboratory did not perform at least 6 months the calibration verification procedures for Lytes by the Dimension EXL 200 system.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 routine chemistry calibration verification records review (year 2018-2019) of the Dimension EXL-200 system and interview with the laboratory director on August 2, 2019 at 10:00 A.M., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by the Dimension EXL 200 system. Refer to D5439.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on routine chemistry calibration verification records review (year 2018-2019) of the Dimension EXL-200 system and interview with the laboratory director on August 2, 2019 at 10:00 A.M., it was determined that the laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by the Dimension EXL 200 system. Refer to D5439.