

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1084511	(X3) Date Survey Completed 11/22/2022
Name of Provider or Supplier Laboratorio Clinico Pastillo	Street Address, City, State Carr Pr-1 Km 113 Hm 6 Bo Cintrona, Juana Diaz, 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 reviewed, laboratory director and general supervisor interview at 11:30 AM; it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the Lipid Panel performed in the Daytona analyzer by Randox. The findings include: a. On November 22, 2022 at 10:00 AM, the quality control records showed that the</p>

laboratory did not perform at least every 6 months the calibration verification procedures for the Lipid Panel tests by the Daytona system. The quality control showed that the las linearity verification was on november 16, 2022. b. The calibration verification before november 16, 2022 was requested. The laboratory general supervisor confirmed on november 22, 2022 at 10:13 am that the calibration verification from January 2022 to November 2022 was not available. 2. The laboratory general supervisor and laboratory director confirmed on November 22, 2022, that the only records for the calibration verification procedures of those tests were performed on november 16, 2022. 3. The laboratory processed and reported 3,120 out of 3,120 Lipid Panel tests by the Daytona system from January 1, 2022 to November 15, 2022.

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 quality control records reviewed and laboratory director interview on November 22, 20212 at 12:00 PM, it was found that the laboratory director did not assure that quality control procedures related to calibration verification procedures were followed. Refer to D5439.