

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0689663	(X3) Date Survey Completed 12/19/2023
Name of Provider or Supplier Lab Clinico Bayamon	Street Address, City, State Calle Parque Esq Rossi Local 4, Bayamon, 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 hematology quality control records review, procedural manual of the instrument and laboratory director interview on December 19, 2023 at 1:53 PM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the Sysmex XN-550 system. The findings include: 1. The laboratory uses a Sysmex XN-550 hematology system for CBC (Complete</p>

blood count) patient's tests. 2. On December 19, 2023 at 1:35 PM, the procedural manual of the instrument was review and showed that the laboratory must perform the calibration verification procedures each six months. 3. On December 19, 2023 at 1:47 PM, the quality control was reviewed. From February 24, 2022 to December 20, 2023 the laboratory did not perform at least every 6 months the calibration verification procedures for the Sysmex XN-550 hematology system since October 12, 2021. 4. The laboratory director confirmed on December 19, 2023 at 1:53 PM that the laboratory did not perform at least 6 months the calibration verification procedures for the Sysmex XN-550 system. Since January 2022 to December 19, 2023 the laboratory processed and reported approximately 20,000 patient's samples. 5. The laboratory did not verify whether the test system is providing accurate results throughout the reportable range.

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 hematology specialty, records review (year 2022 and 2023), procedural manual of the instrument and interview with the laboratory director on December 19, 2023 at 3:16 PM; it was determined that the laboratory director failed to ensure that the calibration verification of the Sysmex XN-550 were performed. Refer to D5439.