

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0958774	(X3) Date Survey Completed 02/14/2025
Name of Provider or Supplier Laboratorio Clinico Vital Care	Street Address, City, State Carr 682 Km 4, Hm 9, Bo Garrochales, Arecibo, 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>(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 lack of hematology calibration verification records, manufacturer's instructions, and laboratory technical consultant interview on February 14, 2025 at 12:45 P.M., it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's instructions (every six months) for the hematology tests performed by the Cell Dyn 1700 hematology system. The findings include: 1. The laboratory uses a Cell Dyn 1700 hematology system for CBC (Complete blood count) patient's tests. 2. Review of the manufacturer's instructions on February 14, 2025 at 12:45 P.M. showed that the laboratory must perform the calibration verification procedures every six</p>

months. 3. On February 14, 2025 at 12:50 P.M., the calibration verification records of Cell Dyn 1700 hematology system showed that the laboratory did not perform at least every 6 months the calibration verification procedures. The last calibration verification procedures were performed on November 2023. 4. The laboratory processed and reported 1,152 CBC patient samples from June 2024 to February 14, 2025. 5. The laboratory technical consultant confirmed on February 14, 2025 at 12:50 P.M, that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn 1700 hematology system.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on white blood cells (WBC) differential results comparison records review (year 2024-2025) and laboratory technical consultant supervisor interview on February 14, 2025 at 11:30 A.M., it was determined that the laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. The findings include: 1. The laboratory performed automatic cell differential by Cell Dyn 1700 hematology system. 2. The WBC differential results comparison records showed that the laboratory did not evaluated twice a year the relationship of the WBC differential results between the manual method and the Cell Dyn 1700 system since November 2023. 3. The laboratory technical consultant stated on February 14, 2025 at 11:30 A.M. that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system since Novemver 2023.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on the preventive maintenance area records reviewed (year 2024-2025) and interview with the laboratory technical consultant on February 14, 2025 at 11:00 AM; it was determined that the laboratory use whiteout for making corrections on the laboratory preventive maintenance work sheets (temperatures, preventive maintenance of the test systems) the year 2024. The findings include: 1. On February 14, 2025 at 11:00 AM the preventive maintenance records of area was reviewed and showed that the laboratory used whiteout to make corrections on the laboratory preventive maintenance work sheets during the year 2024. 2. On February 14, 2025 at 11:00 AM , the laboratory technical consultant confirmed that the laboratory use

whiteout to make corrections in the preventive maintenance records during the year 2024.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(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 control records (year 2024) and interview with the laboratory technical consultant on February 14, 2025 at 1:00 P.M.; it was determined that the laboratory director did not ensure that the quality control that were establish were follow. D5439, D5775 and D5787.