

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0658065	<b>(X3) Date Survey Completed</b> 05/14/2025
<b>Name of Provider or Supplier</b> Lab Clinico Defillo Franceschi	<b>Street Address, City, State</b> Calle Luis Munoz Rivera #147, Guayanilla, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clinico Defillo Franceschi on May 14, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on May 14, 2025.
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 routine chemistry calibration verification records review (years 2024-2025) and interview with the laboratory director on May 14, 2025, at 11:15 AM, it was determined that the laboratory did not perform, at least every six months, the</p>

calibration verification procedures for sodium (Na+), potassium (K+), and chloride (Cl-) tests, when processed and reported 8,001 out of 8,001 electrolytes patient's test from January 1, 2024, to April 30, 2025. The findings include: 1. The laboratory used the Ortho Vitros 250 Chemistry Analyzer to perform Na+, K+, and Cl- tests. (Reviewed on May 14, 2025, at 11:15 AM) 2. The laboratory performed Na+, K+, and Cl- calibration verification procedures in December 2023. (Reviewed on May 14, 2025, at 11:18 AM) 3. Review of routine chemistry calibration verification records showed that the laboratory did not perform Na+, K+, and Cl- calibration verification procedure in June 2024 and December 2024. (Reviewed on May 14, 2025, at 11:20 AM) 4. The laboratory processed and reported 8,001 out of 8,001 Na+, K+, and Cl- patient's test from January 1, 2024, to April 30, 2025. (Reviewed on May 14, 2025, at 11:25 AM) 5. The laboratory director confirmed on May 14, 2025, at 11:30 AM, that the laboratory failed to perform, at least every 6 months, the calibration verification procedures for Na+, K+, and Cl- tests.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(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 routine chemistry quality control records review (years 2024-2025), and interview with the laboratory director on May 14, 2025, at 11:30 AM, it was determined that the laboratory director failed to ensure that the laboratory general supervisor performs, at least every 6 months, the calibration verification procedure for Na+, K+, and Cl- tests. Refer to D6144.

**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 (years 2024-2025) and laboratory director interview on May 14, 2025, at 11:30 AM, it was determined that the laboratory general supervisor failed to fulfill her responsibility to ensure at least every 6 months, the calibration verification procedures for sodium (Na+), potassium (K+), and chloride (Cl-). Refer to D5439.