

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658214	(X3) Date Survey Completed 11/03/2021
Name of Provider or Supplier Laboratorio Clinico Jelmap	Street Address, City, State Degetau 33, 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on hematology calibration records reviewed (years 2019-2021) and laboratory director interview on November 2, 2021 at 10:30 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Coulter Act 2 diff hematology system. The findings include: 1. The laboratory uses a Coulter Act 2 diff hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that the laboratory must perform the calibration verification procedures each six months. 3. From May 5, 2019 to November 3, 2021, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Coulter Act 2 diff hematology system. The calibration verification procedures were done on May 3, 2019, December 2, 2019 and February 2, 2020. 4. The laboratory processed and reported Three thousand eight hundred fifty three (3,853) Complete blood count (CBC) patient's samples from February 3, 2020 to November 2, 2021. (1,859 year 2020 and 1,994 year 2021) 5. The laboratory director confirmed on November 2, 2021</p>

that the laboratory did not perform at least every 6 months the calibration verification procedures for the Coulter Act 2 diff hematology 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 hematology calibration records reviewed (years 2019-2021) and laboratory director interview on November 2, 2021 at 10:30 AM, it was found that the laboratory director did not assure that quality control procedures related to calibration verification procedures were followed. The findings include: 1. The laboratory did not perform, each six months, calibration verification procedures for hematology. Refer to D5437.

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 hematology calibration records reviewed (years 2019-2021) and laboratory director interview on November 2, 2021 at 10:30 AM, it was determined that the general supervisor did not assure that quality control procedures related to calibration and calibration verification procedures were followed. Refer to D5437.