

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0899990	(X3) Date Survey Completed 08/09/2018
Name of Provider or Supplier Laboratorio Clinico Y Bacteriologico Santiago	Street Address, City, State Carretera 111 Km 51 Hm 7 Bo Caguana, Utuado, 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 verification records review (2017-2018), laboratory general supervisor and laboratory director interview on August 9, 2018 at 11:30 A.M., it was determined that the laboratory failed to perform the calibration verification procedures at least the frequency recommended by the manufacturer (annually) . The findings include : 1. The laboratory acquired in May 2017 a new Sysmex XS 1000i to perform hematology tests. 2. Review the hematology calibration verification records , showed that the laboratory did not perform the calibration verification procedures of the hematology system since May 9, 2017. 3. The laboratory general supervisor confirmed on August 9, 2018 at 11:3. A.M., that the laboratory did not perform the calibration verification procedures as least the frequency recommended by the manufacturer (annually) . 4. The laboratory performed and reported 9,239 hematology patient samples (Complete blood cell count) in 2017.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on hematology calibration verification records (2017-2018) and laboratory director interview on August 9, 2018 at 11:30 A.M., it was determined that the laboratory failed to ensure compliance with requirements for analytic systems. The findings include: 1. The laboratory did not perform the hematology calibration verification procedures as least the frequency recommended by the manufacturer (annually) . 2. The laboratory director confirmed on August 9, 2018, that the laboratory failed to ensure compliance with requirements for analytic systems. Refer to D5437.

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 verification records review (2017-2018) and laboratory director interview on August 9, 2018 at 11:30 A.M. , it was determined that the laboratory director failed to ensure compliance with the requirements for analytic system. 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 verification records and laboratory director interview on August 9, 2018 at 11:30 A.M., it was determined that the general supervisor failed to ensure compliance with the requirements for analytic system. The finding includes: 1. The laboratory general supervisor confirmed on August 9, 2018 at 11:30 A.M. ,that the laboratory failed to ensure compliance with the requirements for analytic system. Refer to D5437.