

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0684519	(X3) Date Survey Completed 12/26/2019
Name of Provider or Supplier Laboratorio Clinico Avanzado Emmanuel, Inc	Street Address, City, State Calle Palmer #58, Toa Alta, 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
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on hematology quality control records review (year 2018-2019) and laboratory director interview at 9:50 A.M. on December 26, 2019, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. The finding includes: 1. The laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Coulter Act 5 diff hematology system. Refer to D5405.</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instructions, hematology quality control records review (years 2018-2019) and laboratory director interview at 9:50 a.m. on December 27, 2019, it was determined that the laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Coulter Act 5 diff hematology system. The findings include: 1. The laboratory uses Coulter</p>

Act 5 diff to perform hematology patient tests. 2. The manufacturer establishes that three levels of control material (low, normal and high) must be included each day of testing. 3. Review of hematology quality control records from January 2018 to December 26, 2019, showed that the laboratory did not include the three levels of controls from May 6, 2018 to May 17, 2018. 4. The laboratory processed and reported 149 Complete Blood Count patient's samples those days. 5. The laboratory director confirmed that the laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Coulter Act 5 diff hematology system.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on hematology quality control records review (2018-2019) and interview with the laboratory director on December 16, 2019 at 11:00 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements for hematology. The finding includes: 1. The laboratory director failed to ensure compliance with the hematology requirements. Refer to D6093.