Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0664123	09/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Mhc Sabana Grande	Km 1 Hm 0, Carr 368, Bo Machuchal, Sabana Grande, 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	HEMATOLOGY CFR(s): 493.1215 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. This CONDITION is not met as evidenced by: Based on manufacturer's instructions, hematology quality control records review in years 2017-2018, calibration verification procedures records review in years 2016-2018 and laboratory director interview on September 21, 2018 at 10:15 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. Refer to D5437 (the laboratory failed to perform the calibration verification procedures with at least the frequency recomended by the manufacturer's (each six months) for the hematology test performed by the Act 5 diff CP system) and D5447 (the laboratory failed to include three levels of controls when complete blood count (CBC) patient's samples tests were performed by Act 5 diff CP system).
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, hematology calibration verification records review in years 2016-2018 and laboratory director interview on September 21, 2018 at 10:15 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recomended by the manufacturer's (each six months) for the hematology test performed by the Act 5 diff CP system. The findings include: 1. The laboratory uses an Act 5 diff CP hematology system for CBC (Complete blood count) patient's samples tests. 2. The manufacturer's instructions establishes that for the Act 5 diff CP system, the calibration verification procedures must be perform each six months. 3. Review of hematology calibration verification records from December 2016 to September 2018, showed that the laboratory failed to perform at least every six months the calibration verification procedures for the Act 5 diff CP hematology system. The calibration verification procedures was 10/31/2016 and 2/2018. 4. The laboratory director confirmed on September 21, 2018, that the laboratory did not perform at least six months the calibration verification procedures for Act 5 diff CP hematology system. 5. The laboratory processed and reported nine hundred (900) Complete blood count patient's samples tests since June 2017.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, hematology quality control records review in years 2017-2018 and laboratory director interview at 10:15 AM on September 21, 2018, it was determined that the laboratory failed to include three levels of controls when complete blood count (CBC) patient's samples tests were performed by Act 5 diff CP system. The findings include: 1. The laboratory uses the Act 5 diff CP hematology system to perform Complete blood count (CBC) patient's samples. 2. The manufacturer's 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 2017 to August 2018, showed that the laboratory did not have evidence that include the three levels of controls in the following days: Date Control Processed #CBC's 1/11/2018 Only Low 2 3/28/2018 Only Normal 2 4/10/2018 Only Normal 3 5/9/2018 Only Normal 1 4. The laboratory processed and reported eight (8) complete blood count (CBC's) patient.s samples tests those days. 5. The laboratory director confirmed on September 21, 2018, that the laboratory did not include the three levels of controls each day of testing.
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 manufacturer's instructions, hematology quality control records review in years 2017-2018, calibration verification procedures records review in years 2016-2018 and laboratory director interview at 10:15 AM on September 21, 2018, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for the hematology specialty. The findings include: 1. The laboratory failed to perform the calibration verification procedures with at least the frequency recomended by the manufacturer's (each six months) for the hematology test performed by the Act 5 diff CP system. Refer to D5437. 2. The laboratory failed to include three levels of controls when complete blood count (CBC) patient's samples tests were performed by Act 5 diff CP system. Refer to D5447.
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 manufacturer's intructions, hematology quality controls records review in 2017-2018, calibration verification procedures records review in years 2016-2018 and laboratory director interview at 10:15 AM on September 21, 2018, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to perform the calibration verification procedures with at least the frequency recomended by the manufacturer's (each six months) for the hematology test performed by the Act 5 diff CP system. Refer to D5437. 2. The laboratory failed to include three levels of controls when complete blood count (CBC) patient's samples tests were performed by Act 5 diff CP system. Refer to D5447.