Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658031	10/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Boqueron, Inc	Munoz Rivera #63, Boqueron, 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 hematology quality control records review in years 2017-2018 and laboratory director interview at 10:30 a.m. on October 5, 2018, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for PT-PTT coagulation system. Refer to D5401 (The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio) and Refer to D5469 (The laboratory failed to verify the criteria for acceptability of the hematology control materials used by the Stago Star 4 coagulation system).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of hematology quality control records and laboratory director interview at 11:00 AM on October 5, 2018, it was determined that the laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). The findings include: 1. The laboratory uses Stago Start 4 to perform PT

	(prothrombin time) patient's samples tests. 2. The laboratory placed in routine use the following Sta Neoplastine Cl Plus 5 reagents: Lot # Exp. Date 114575 9/2017 250454 5/2018 253025 11/2019 3. The laboratory did not establish a normal population (PT) mean for each new lot number. 4. The laboratory director stated that unknown what is the former laboratory PT mean that the system used. 5. The laboratory processed and reported approximately three hundred forty eight (348) PT patients samples tests from Janaury 2017 to September 2017, two hundred eighty one (281) PT patients samples tests from October 2018 to May 2018 and one hundred fifty (150) PT patients samples tests from June 2018 to September 2018.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control records review in years 2017-2018 and laboratory director interview at 10:30 AM on October 5, 2018, it was determined that the laboratory failed to verify the criteria for acceptability of the hematology control materials used by the Stago Star 4 coagulation system. The findings include: 1. The laboratory uses a Stago Star 4 coagulation system to perform PT and PTT samples patient's tests. 2. Review of hematology quality controls records from January 2017 to September 2018, showed that the laboratory did not evaluate the following studies controls lot numbers (114310, exp. 9/2017 and 252096, exp. 4/30/2019), prior to use respectively. 3. The laboratory director stated on October 5, 2018, that the laboratory failed to verify the criteria for aceptability of the hematology control materials used by the Stago Star 4 coagulation system. 4. The laboratory processed and reported seven hundred sixty nine (769) PT and PTT samples patient's tests.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: A. Based on Quality Assessment (QA) procedure manual, Quality Assessment records review in years 2017-2018 and laboratory director interview at 10:30 AM on October 5, 2018, it was determined that the laboratory failed to follow the established Quality

	Assessment Program to monitor and evaluate the following requirement for post analytic system: Turn around time (TAT). The findings include: 1. The Quality Assessment (QA) procedure manual states that evaluations of the laboratory turn around time (TAT) is done annually. 2. Review of Quality Assessment records from January 2017 to September 2018, showed that the laboratory did not monitor and evaluate the TAT since Janaury 2017. 3. The laboratory director confirmed on October 5, 2018 that the laboratory did not monitor and evaluate the TAT since January 2017. B. Based on Quality Assessment (QA) procedure manual, Quality Assessment records review in years 2017-2018 and laboratory director interview on October 5, 2018 at 10:30 AM, it was determined that the laboratory failed to evalute and define twice a year the relationship between the automatic and manual calculation of the hematology media (HCT (hematocrit), MCH (Mean Corpuscular Hematocrit) and MCHC (Mean Corpuscular Hematocrit Concentration)) and INR (International Normalized Ratio) calculated values. The findings includes: 1. The Quality Assessment manual established that the laboratory evaluate twice a year the relationship between the automatic and manual (HCT, MCH, MCHC) and INR calculated values. 2. Review of Quality Assessment records from January 2017 to September 2018, the laboratory failed to evaluate and define twice a year the relationship between the automatic and manual calculation of the hematology media (HCT, MCH and MCHC) and INR calculated values in 2017. 3. The laboratory director confirmed on October 5, 2018 that the laboratory did not evaluate and define twice a year the relationship between the automatic and manual calculation of the hematology media (HCT, MCH and MCHC) and INR calculated values in 2017.. C. Based on Quality Assessment (QA) procedure manual, Quality Assessment records review in years 2017-2018 and laboratory director interview on October 5, 2018 at 10: 30 AM, it was determined that the laboratory failed to evalute and define twice a year the relationship between the automatic and manual calculation of the routine chemistry calculated values. The findings includes: 1. The Quality Assessment manual established that the laboratory evaluate twice a year the relationship between the automatic and manual routine chemistry calculated values. 2. Review of Quality Assessment records from January 2017 to September 2018, the laboratory failed to evaluate and define twice a year the relationship between the automatic and manual calculation of the routine chemistry calculated values in 2017. 3. The laboratory director confirmed on October 5, 2018 that the laboratory did not evaluate and define twice a year the relationship between the automatic and manual calculation of the routine chemistry calculated values in 2017.
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 in years 2017-2018 and laboratory director interview at 10:30 a.m. on October 5, 2018, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D 6093 and D 6094.
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 quality control records review in years 2017-2018 and laboratory director interview on October 5, 2018 at 10:30 AM, it was determined that the laboratory director failed to ensure compliance with requirements for analytic systems. Refer to D5401 and D5469.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 Quality Assessment records review in years 2017-2018 and laboratory director interview at 10:30 AM on October 5, 2018, it was determined that the laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5891.
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 quality control records review in years 2017-2018 and laboratory director interview on October 5, 2018 at 10:30 AM, it was determined that the laboratory general supervisor failed to ensure compliance with requirements for analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401. 2. The laboratory failed to verify the criteria for acceptability of the hematology control materials used by the Stago Star 4 coagulation system. Refer to D5469.