Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0883986	03/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Punta Santiago	Calle Aduana 1, Bo Punta Santiago, Humacao, 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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on P.R.Proficiency Testing Program (PRPTP) records (years 2017, 2018 and 2019) review and laboratory director interview on March 28, 2019 at 9:20 AM, it was determine that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in the 2017 first event of proficiency testing for creatinine and sodium. The findings include: 1. On March 28, 2019 at 9:20 AM, reviewed the PRPTPP showed that the laboratory it obtained an unsatisfactory results in the 2017 first event of proficiency testing for creatinine (60%) and sodium (60 %). 2. The laboratory director confirmed on March 28, 2019 at 9:20 AM, that the laboratory did not take nor document corrective actions in this event (February 2017).
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records (years 2017,

	2018 and 2019) and laboratory director interview on March 28, 2019 at 9:20 AM, it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. PRPTP records were reviewed for 2017, 2018 and 2019. 2. On March 28, 2019 at 9:20 AM, the PRPTP records showed that the laboratory did not have in record the following year 2017 proficiency testing event records: third testing event for routine chemistry, urinalysis and endocrinology tests (October 2017); second and third testing events for hematology (July and November 2017) and second and third testing events for syphilis serology test (August and December 2017). 3. The laboratory director confirmed on on March 28, 2019 at 9:20 AM, that the laboratory did not have available those PRPTP testing records.
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 CBC quality control records, Coulter Act5 diff Control Plus manufacturer instructions review, direct observation and laboratory director interview on March 28, 2019 at 11:15 AM, it was determined that the laboratory failed to meet the analytic system requirements for the CBC tests. Refer to D 5417 (The laboratory used CBC control materials that exceeded the expiration date from March 6, 2019 to March 27, 2019). Refer to D 5469 (The laboratory did not verify the manufacturer's statistical values of every new the lot numbers of the CBC control materials used by the Coulter Act 5 diff system from January 8, 2018 to December 21, 2018). Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the CBC controls materials from January 21, 2018 to March 27, 2019).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) 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. This STANDARD is not met as evidenced by: Based on Rapid plasma reagin (RPR) quality control records, Detector RPR manufacturers instructions review and laboratory director interview on March 28, 2019 at 11:48 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 43 out of 43 patient specimen were tested for syphilis serology by RPR method from May 1, 2018 to March 27, 2019. The findings include: 1. The manufacturer's instruction establishes that three levels of control material (non reactive, minimal reactive and reactive) must be included each day of testing. 2. From from May 1, 2018 to March 27, 2019, the RPR quality control records showed that the laboratory did not include each day of testing the minimal reactive control material when it processed and reported 43 out of 43 patients specimens for syphilis serology by RPR method. 3. The laboratory director confirmed on March 28, 2019 at 11:48 AM, that the laboratory did not include each day of testing the minimal reactive

	control material. She stated that the laboratory includes each day of testing the non reactive and the reactive control material.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on CBC quality control records, Coulter Act5 diff Control Plus control materials, direct observation and laboratory director interview on March 28, 2019 at 11:15 AM, it was determined that the laboratory used the CBC control materials with exceeded expiration date. The findings include: 1. The laboratory used the Coulter Act5 diff Control Plus to monitor system performance of the Coulter Act 5 system for the CBC tests. 2. On March 28, 2019 at 11:15 AM, it observed that the laboratory used the three levels of Coulter Act5 diff Control Plus control materials (Lot 381118, 361118 and 37118) with exceeded expiration date from March 6, 2019 to March 27, 2019. 3. The laboratory director confirmed on March 28, 2019 at 11:15 AM, that the laboratory used the CBC control materials (Lot 381118, 361118 and 37118) with exceeded expiration date from March 6, 2019 to March 27, 2019. 4. The laboratory processed and reported 87 out of 87 patients specimens for CBC tests from March 6, 2019 to March 27, 2019.
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 complete cell count (CBC) quality control records review and interview with the laboratory director on March 29, 2019 at 10:30 AM, it was determined that the laboratory failed to verify the manufacturer's statistical values of every new the lot numbers of the CBC control materials used by the Coulter Act 5 diff system from January 8, 2018 to December 21, 2018. The finding include: 1. On March 29, 2019 at 10:30 AM, The CBC quality control records showed that the laboratory did not verify the manufacturer's statistical values of following new the lot numbers of the CBC control materials used by the Coulter Act 5 diff system from January 8, 2018 to December 21, 2018: a. Lot numbers 087500, 020112 and 077500; used from January

	8, 2018 to February 28, 2018. b. Lot numbers 360520, 370520 and 380520; used from March 1, 2018 to April 30, 2018. c. Lot numbers 380522, 370522 and 360522; used from May 1, 2018 and June 29, 2018. d. Lot numbers 370718, 360718 and 350119; used from July 2, 2018 to August 31, 2018. e. Lot numbers 360918, 380918 and 370918; used from September 1, 2018 to October 31, 2018. f. Lot numbers 381118, 371118 and 361118; used from November 2, 2018 to December 21, 2018. g. Lot numbers 380119, 370119 and 360119, used from December 22, 2018 to March 27, 2019. 2. The laboratory director confirmed on March 29, 2019 at 10:30 AM, that the laboratory did not verify the manufacturer's statistical values of those new the lot numbers of the CBC control materials prior to place in routine use. 3. The laboratory processed and reported 3,254 patients CBC tests in the hematology area during the year 2018.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on CBC quality control records, Coulter Act5 diff Control Plus manufacturer instructions review, direct observation and laboratory director interview on March 28, 2019 at 11:15 AM, it was determined that the laboratory failed to follow the manufacturer's specifications for using the CBC controls materials from January 21, 2018 to March 27, 2019. The findings include: 1. The laboratory analyzed and reported the CBC patient's specimens by the Coulter Act5 diff system. 2. The CBC quality control records showed that the laboratory used the Coulter Act5 diff Control Plus from January 8, 2018 to March 27, 2019. 3. The Coulter Act5 diff Control Plus manufacturer instructed the laboratory to use the control materials with 15 consecutive days open-vial stability. 4. On March 28, 2019 at 11:15 AM, it observed that the laboratory used the levels of CBC control material (Lot 381118, 361118 and 37118) with exceeded the 15 days open vial stability days. Those lot numbers vials were placed in use since December 21, 2018 and used until March 27, 2019. 5. The laboratory director confirmed on March 28, 2019 at 11:15 AM, that the laboratory used the CBC control materials (Lot 381118, 361118 and 37118) with more than 15 days open vial stability. She stated that the laboratory uses for every two moths, one box of Coulter Act5 diff Control Plus (the control material box includes materials to monitor the CBC system performance for 30 days). 6. On March 28, 2019 at 11:15 AM, it observed that the laboratory used the the three levels of CBC control material (Lot 381118, 361118 and 37118) with exceeded expiration date from March 6, 2019 to March 27, 2019. Refer to D 5417. 7. The laboratory processed and reported 87 out of 87 patients specimens for CBC tests from March 6, 2019 to March 27, 2019.
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 Puerto Rico Proficiency Testing Program (PRPTP) records (years 2017, 2018 and 2019) , CBC quality control records, Coulter Act5 diff Control Plus manufacturer instructions review, direct observation, Rapid plasma reagin (RPR) quality control records, Detector RPR manufacturers instructions review and laboratory director interview on March 28, 2019 at 11:48 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory records retention, proficiency testing program and analytical system requirements. The findings include: 1. Refer to D 6079 (The laboratory director failed to ensure that the retain proficiency testing records for at least 2 years). 2. Refer to D 6092 (The laboratory director failed to take and document corrective actions when the laboratory obtained an unsatisfactory results in the 2017 first event of proficiency testing for creatinine and sodium). 3. Refer to D 6093 (The laboratory director failed to ensure compliance with the requirements for the analytic systems of CBC and RPR tests).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records (years 2017, 2018 and 2019) and laboratory director interview on March 28, 2019 at 9:20 AM, it was determined that the laboratory director failed to ensure that the retain proficiency testing records for at least 2 years. Refer to D 3037.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on P.R.Proficiency Testing Program (PRPTP) records (years 2017, 2018 and 2019) review and laboratory director interview on March 28, 2019 at 9:20 AM, it was determine that the laboratory director failed to take and document corrective actions when the laboratory obtained an unsatisfactory results in the 2017 first event of proficiency testing for creatinine and sodium. Refer to D 2094.
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 CBC quality control records, Coulter Act5 diff Control Plus manufacturer instructions review, direct observation, Rapid plasma reagin (RPR) quality control records, Detector RPR manufacturers instructions review and laboratory director interview on March 28, 2019 at 11:48 AM, it was determined that laboratory director failed to ensure compliance with the requirements for the analytic systems. The findings include: 1. Refer to D 5024 (The laboratory failed to meet the analytic system requirements for the CBC tests). 2. Refer to D 5405 (The laboratory failed to follow the manufacturer's instruction when 43 out of 43 patient specimen were tested for syphilis serology by RPR method from May 1, 2018 to March 27, 2019).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on CBC quality control records, Coulter Act5 diff Control Plus manufacturer instructions review, direct observation, Rapid plasma reagin (RPR) quality control records, Detector RPR manufacturers instructions review and laboratory director interview on March 28, 2019 at 11:48 AM, it was determined that testing personnel failed to ensure compliance with the requirements for the analytic systems. The findings include: 1. Refer to D 5405 (The laboratory failed to follow the manufacturer's instruction when 43 out of 43 patient specimen were tested for syphilis serology by RPR method from May 1, 2018 to March 27, 2019). 2. Refer to D 5417 (The laboratory used CBC control materials that exceeded the expiration date from March 6, 2019 to March 27, 2019). 3. Refer to D 5469 (The laboratory did not verify the manufacturer's statistical values of every new the lot numbers of the CBC control materials used by the Coulter Act 5 diff system from January 8, 2018 to December 21, 2018). 4. Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the CBC controls materials from January 21, 2018 to March 27, 2019).