Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1024025	05/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Laurel	Ave Laurel Aq 35 Santa Juanita, Bayamon, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on hematology procedures manual, Coulter Act 5 diff calibration records (years 2018 and 2019) review and laboratory director interview on May 17, 2019 at 11:48 AM, it was determined that the laboratory failed to perform every 6 months the calibration procedures of the Coulter Act 5 diff system when 1,585 complete blood count (CBC) patients specimens were tested and reported from February 3, 2019 to May 17, 2019. The findings include: 1. The laboratory processed and reported patients specimens for CBC tests by the Coulter Act 5 diff system. 2. The hematology procedures manual requires to perform every 6 months the calibration procedures for

	the Coulter Act 5 diff system. 3. On May 17, 2019 at 11:48 AM, the Coulter Act 5 diff calibration records showed that the laboratory did not perform every 6 months the calibration procedures. The laboratory performed the last calibration for the Coulter Act 5 diff system on August 2, 2018. 4. The laboratory tested and reported 1,585 CBC patients specimens from February 3, 2019 to May 17, 2019 by the Coulter Act 5 diff system.
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: 1. Based on manufacturer's instructions, syphilis serology testing records review (years 2018 to 2019) and laboratory director interview on May 17, 2019 at 12:22 PM, it was determined that the laboratory failed to follow manufacturer's instructions when 47 out of 95 patients specimens were tested and reported for syphilis serology test by TECO RPR (Rapid plasma reagin) method from January 8, 2019 to April 9, 2019. The findings include: a. The TECO manufacturer's establishes that the RPR tests must be performed at room temperature range from 23 C to 29 C . b. On May 17, 2019 at 12: 22 PM, the syphilis serology testing records showed that 47 out of 95 patients specimens were processed and reported for RPR at room temperature of 22 C from January 8, 2019 to April 9, 2019. c. The laboratory director confirmed on May 17, 2019 at 12:22 PM, that the syphilis serology testing records showed that those patients specimens were processed and reported for RPR at room temperature of 22 C. 2. Based on Vitamin D Cobas manufacturer's instruction, PreciControl Varia package insert, Vitamin D quality control records (years 2017 to 2019) and testing personnel (MT #1) interview on May 17, 2019 at 10:40 AM, it was determined that the laboratory failed to follow manufacturers instruction for quality control procedure when 1,097 out of 1,097 patients specimens were tested and reported for Vitamin D from November 15, 2017 to May 13, 2019 by the Elecsys 2010 system. The findings include: a. The laboratory tested and reported the patients specimens for Vitamin D by the Elecsys 2010 system. b. The Vitamin D Cobas manufacturer instructed the laboratory for quality contro, to use the Preci Control Varia. The manufacturer requires that controls for the various concentration ranges should be run individually at least once every 24 hours when the tests is in use. c. The Preci Control Varia package insert showed control materials with three concentration ranges for the Vitamin D test. d. On May 17, 2019 at 10:40 AM, the Vitamin D quality control records showed that the laboratory run two levels of control material when patients specimens were tested and reported for Vitamin D by the Elecsys 2010 system. e. The testing personnel (MT #1) confirmed that the laboratory run two control materials (low and high levels) when patients specimens were tested and reported for Vitamin D by the Elecsys 2010 system. f. The laboratory processed and reported 1,097 out of 1,097 patients specimens for Vitamin D from November 15, 2017 to May 13, 2019 by the Elecsys 2010 system.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on room temperature records (from years 2017 to 2019) for the routine chemistry and endocrinology area and testing personnel (TM#1) interview on May 17, 2019 at 9:30 AM, it was determined that the laboratory failed to monitor the room temperature where 6,126 routine chemistry tests and 3,591 endocrinology and special chemistry tests; triiodothyronine uptake (T3 uptake) , Total Thyroxin (T4), Thyroxin free (T4 free), Thyroid Stimulating hormone (TSH) and prostatic specific antigen (PSA) were processed and reported from January 1, 2018 to December 31, 2018. The findings include: 1. The laboratory processed the routine chemistry tests by the Integra 400 system, the endocrinology and special chemistry tests by the Elecsys 2010 system, both systems located in the same room. 2. On May 17, 2019 at 9:30 AM, the room temperature records of the routine chemistry, endocrinology and special chemistry tests area did not showed the 2018's room temperature chart. 3. The testing personnel (TM#1) confirmed on May 17, 2019 at 9:30 AM, that the room temperature records did not include the 2018's room temperature chart of that area. 4. The laboratory processed and reported the following patients tests results from January 1, 2018 to December 31, 2018: 6,126 routine chemistry tests; and 3,591 endocrinology and special chemistry tests.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by:

	1. Based on Integra 400 system calibration verification records (years 2017, 2018 and 2019) reviewed and testing personnel (TM#1) interview on May 17, 2019 at 9:05 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry tests when it processed and reported the following patients specimens from September 17, 2017 to February 25, 2019 by the Integra 400 system: 2,629 comprehensive metabolic panel (CMP) , 2,415 lipid panel and 1,978 glycohemoglobin. The findings include: a. On May 17, 2019 at 9:05 AM, the Integra 400 system calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests from September 17, 2017 to February 25, 2019. The laboratory performed the calibration verification for the routine chemistry tests on March 17, 2017 and on February 26, 2019. b. The personnel (TM#1) confirmed on May 17, 2019 at 9:05 AM, that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests from September 17, 2017 to February 25, 2019. c. The laboratory processed and reported the following patients specimens from September 17, 2017 to February 25, 2019 by the Integra 400 system: 2,629 CMP, 2,415 lipid panel and 1,978 glycohemoglobin. 2. Based on Elecsys 2010 system calibration verification records (years 2017, 2018 and 2019) reviewed and testing personnel (TM#1) interview on May 17, 2019 at 10:00 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the special chemistry and endocrinology tests when it processed and reported the following patients specimens from November 15, 2017 to May 13, 2019 by the Elecsys 2010 system: 779 triiodothyronine uptake (T 3 uptake), 957 Total Thyroxin (T4), 533 Thyroxin free (T4F) , 1,126 Thyroid Stimulating hormone (TSH) , 719 prostatic specific antigen (PSA) and 1,097 Vitamin D 1,097. The findings include: a. On May 17, 2019 at 10:00 AM, the Elecsys 2010 system calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests from November 15, 2017 to May 13, 2019. The laboratory performed the calibration verification for the special chemistry and endocrinology tests on May 15, 2017 and on May 14, 2019. b. The personnel (TM#1) confirmed on May 17, 2019 at 10:00 AM, that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests from from November 15, 2017 to May 13, 2019. c. The laboratory processed and reported the following patients specimens from November 15, 2017 to May 13, 2019 by the Elecsys 2010 system: 779 T 3 uptake, 957 T4, 533 T4F, 1,126 TSH, 719 PSA and 1,097 Vitamin D.
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 procedures manual, Coulter Act 5 diff calibration records (years 2018 and 2019), manufacturer's instructions, syphilis serology testing records review (years 2018 to 2019), Vitamin D Cobas manufacturer's instruction, PreciControl Varia package insert, Vitamin D quality control records (years 2017 to 2019), room temperature records (from years 2017 to 2019) for the routine chemistry and endocrinology area, Integra 400 system calibration verification records (years 2017,

	2018 and 2019) , Elecsys 2010 system calibration verification records (years 2017, 2018 and 2019) reviewed, testing personnel (MT #1) and laboratory director interview on May 17, 2019 at 12:22 PM, it was determined that laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system from September 17, 2017 to May 13, 2019. Refer to D 6093 (The laboratory director failed to comply with the analytic system requirements from September 17, 2017 to May 13, 2019).
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 procedures manual, Coulter Act 5 diff calibration records (years 2018 and 2019), manufacturer's instructions, syphilis serology testing records review (years 2018 to 2019), Vitamin D Cobas manufacturer's instruction, PreciControl Varia package insert, Vitamin D quality control records (years 2017 to 2019), room temperature records (from years 2017 to 2019) for the routine chemistry and endocrinology area, Integra 400 system calibration verification records (years 2017, 2018 and 2019) , Elecsys 2010 system calibration verification records (years 2017, 2018 and 2019) reviewed, testing personnel (MT #1) and laboratory director interview on May 17, 2019 at 12:22 PM, it was determined that the laboratory director failed to comply with the analytic system requirements from September 17, 2017 to May 13, 2019. The findings include: 1. Refer to D 5403 (The laboratory director did not ensure that the calibration procedures for the Coulter Act 5 diff system were performed every six months). 2. Refer to D 5405 (1) (The laboratory director did not ensure that the TECO RPR manufacturer's instructions were followed). 3. Refer to D 5405 (2) (The laboratory director did not ensure that the Vitamin D Cobas manufacturer's instructions were followed). 4. Refer to D 5413 (The laboratory director did not ensure that the room temperature of the to monitor routine chemistry and endocrinology area were monitored). 5. Refer to D 5439 (1) (The laboratory director did not ensure that the the calibration verification procedures for the routine chemistry tests were performed at least every 6 months). 6. Refer to D 5439 (2) (The laboratory director did not ensure that the the calibration verification procedures for the special chemistry and endocrinology tests were performed at least every 6 months).
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on hematology procedures manual, Coulter Act 5 diff calibration records (years 2018 and 2019), manufacturer's instructions, syphilis serology testing records review (years 2018 to 2019), Vitamin D Cobas manufacturer's instruction, PreciControl Varia package insert, Vitamin D quality control records (years 2017 to 2019), room

	temperature records (from years 2017 to 2019) for the routine chemistry and endocrinology area, Integra 400 system calibration verification records (years 2017, 2018 and 2019) , Elecsys 2010 system calibration verification records (years 2017, 2018 and 2019) reviewed, testing personnel (MT #1) and laboratory director interview on May 17, 2019 at 12:22 PM, it was determined that the technical supervisor failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control program from September 17, 2017 to May 13, 2019. Refer to D 6117 (The technical supervisor failed to establish and follow quality control procedures to process and report the following patient tests from September 17, 2017 to May 13, 2019: CBC, RPR, routine chemistry, special chemistry and endocrinology).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on hematology procedures manual, Coulter Act 5 diff calibration records (years 2018 and 2019), manufacturer's instructions, syphilis serology testing records review (years 2018 to 2019), Vitamin D Cobas manufacturer's instruction, PreciControl Varia package insert, Vitamin D quality control records (years 2017 to 2019), room temperature records (from years 2017 to 2019) for the routine chemistry and endocrinology area, Integra 400 system calibration verification records (years 2017, 2018 and 2019) , Elecsys 2010 system calibration verification records (years 2017, 2018 and 2019) reviewed, testing personnel (MT #1) and laboratory director interview on May 17, 2019 at 12:22 PM, it was determined that the technical supervisor failed to establish and follow quality control procedures to process and report the following patient tests from September 17, 2017 to May 13, 2019: CBC, RPR routine chemistry, special chemistry and endocrinology. The finding includes: 1. Refer to D 5403 (The laboratory did not perform every six months the calibration procedures for the Coulter Act 5 diff system). 2. Refer to D 5405 (1) (The laboratory did not follow the TECO RPR manufacturer's instructions). 3. Refer to D 5405 (2) (The laboratory did not follow the Vitamin D Cobas manufacturer's instructions). 4. Refer to D 5413 (The laboratory did not monitor the room temperature of the routine chemistry and endocrinology area). 5. Refer to D 5439 (1) (The laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests). 6. Refer to D 5439 (2) (The laboratory did not perform at least every 6 months the calibration verification procedures for the special chemistry and endocrinology tests).
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 hematology procedures manual, Coulter Act 5 diff calibration records (years 2018 and 2019), manufacturer's instructions, syphilis serology testing records review (years 2018 to 2019), Vitamin D Cobas manufacturer's instruction, PreciControl Varia package insert, Vitamin D quality control records (years 2017 to 2019), room temperature records (from years 2017 to 2019) for the routine chemistry and endocrinology area, Integra 400 system calibration verification records (years 2017, 2018 and 2019) , Elecsys 2010 system calibration verification records (years 2017, 2018 and 2019) reviewed, testing personnel (MT #1) and laboratory director interview on May 17, 2019 at 12:22 PM, it was determined that the testing personnel failed to follow quality control procedures from September 17, 2017 to May 13, 2019. The finding includes: 1. Refer to D 5403 (The laboratory did not perform every six months the calibration procedures for the Coulter Act 5 diff system). 2. Refer to D 5405 (1) (The laboratory did not follow the TECO RPR manufacturer's instructions). 3. Refer to D 5405 (2) (The laboratory did not follow the Vitamin D Cobas manufacturer's instructions). 4. Refer to D 5413 (The laboratory did not monitor the room temperature of the routine chemistry and endocrinology area). 5. Refer to D 5439 (1) (The laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests). 6. Refer to D 5439 (2) (The laboratory did not perform at least every 6 months the calibration verification procedures for the special chemistry and endocrinology tests).