Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658312	09/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Raul Diaz	Ave Jesus T Pinero #265 Hyde Park, Rio Piedras, 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
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 laboratory procedures manual, coagulation quality control records review (from February 1, 2018 to September 19, 2019) and laboratory general supervisor (technical supervisor) interview on September 19, 2019 at 11:12 AM, it was determined that the laboratory failed to monitor and document the dry bath temperature. The findings include: 1. The laboratory procedures manual establishes that the laboratory monitor and document each day of use the dry bath temperature. 2. From February 1, 2018 to September 19, 2019, the laboratory did not monitor and document each day of use the dry bath temperature. 3. The laboratory general supervisor (technical supervisor) confirmed on September 19, 2019 at 11:12 AM, that the laboratory did not monitor and document the dry bath temperature from February 1, 2018. 4. The laboratory processed and reported 135 patients specimens for coagulation tests from February 1, 2019 to September 19, 2019.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of quality control records, written procedures review and laboratory general supervisor (technical supervisor) interview on September 19, 2019 at 10:15 AM, it was determined that the laboratory failed to perform and document the preventive maintenance of urinalysis equipment and instrument (centrifuge and microscope) each day of use. The findings include: 1. The laboratory did not perform and document the preventive maintenance of the centrifuges (Clay Adams) and the microscope (American Optics) each day of use from February 1, 2018 to September 19, 2019. 2. The general supervisor (technical supervisor) confirmed on September 19, 2019 at 10:15 AM, that those preventive maintenance were not perform and document from February 1, 2018 to September 19, 2019. 3. The urinalysis testing records showed that the laboratory performed 1,665 patients specimens for urinalysis from February 1, 2018 to September 19, 2019.
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: Based on hematology quality control records review (from February 1, 2018 to September 19, 2019) and laboratory general supervisor (technical supervisor) interview at 11:25 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the hematology tests processed by the Beckman Coulter AcT Diff 2 system. The findings include: 1. The laboratory uses a Beckman Coulter AcT Diff 2 system for hematology tests. 2. Review the hematology quality control records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the hematology tests processed by Beckman Coulter AcT Diff 2 system since February 1, 2019. The laboratory once perform the calibration verification procedures on June 5, 2018 and September 17, 2019. 3. The laboratory general supervisor (technical

	supervisor) stated on September 19, 2019 at 11:25 AM, that the laboratory did not perform at least 6 months the calibration verification procedures for hematology tests by the Beckman Coulter AcT Diff 2 system. 4. The laboratory processed and reported 2,264 patients specimens for hematology tests from February 1, 2018 to September 19, 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, coagulation and urinalysis quality control records review (from February 1, 2018 to September 19, 2019) records review and laboratory general supervisor interview on September 19, 2019 at 11:50 AM, it was determined that the laboratory director failed to ensure that the analytic requirements for hematology, coagulation and urinalysis. The findings include: 1. The laboratory did not monitor and document the dry bath temperature. Refer to D 5413. 2. The laboratory did not perform and document the preventive maintenance of urinalysis equipment and instrument (centrifuge and microscope) each day of use. Refer to D5429. 3. The laboratory did not perform at least every 6 months the calibration verification procedures for the hematology tests processed by the Beckman Coulter AcT Diff 2 system. Refer to D5439.
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, coagulation and urinalysis quality control records review (from February 1, 2018 to September 19, 2019) and laboratory technical supervisor interview on September 19, 2019 at 11:52 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The technical supervisor failed to ensure compliance with the coagulation analytic system requirement for monitor and document the dry bath temperature. 2. The technical supervisor failed to ensure compliance with the urinalysis analytic system to perform and document the preventive maintenance of urinalysis equipment and instrument (centrifuge and microscope) each day of use. Refer to D5429. 3. The technical supervisor failed to ensure compliance with the hematology analytic system requirement to perform at least every 6 months the calibration verification procedures for the hematology tests processed by the Beckman Coulter AcT Diff 2 system. Refer to D5439.