Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1000674	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Fair View Csp	Carr Pr-845, D-32, Urb Fair View, Trujillo Alto, 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
D0000	An unannounced CLIA Recertification survey was conducted at the Laboratorio Clnico Fair View on December 5, 2024 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on December 5, 2024, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1250 Analytic systems 42 CFR 493.1441 Laboratory Director, High Complexity Testing
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of hematology, urinalysis and endocrinology quality control records and laboratory technical supervisor interview on December 5, 2024 at 2:29 pm, it was determined that the laboratoty failed to meet requirements for analytic systems. Refer to D5413, D5469 and D5479.
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 review of hematology written procedure manual and laboratory technical supervisor interview on December 5, 2024 at 11:58 am, it was determined that the laboratory did not update the hematology procedure manual to reflect the new Sysmex KX21N hematology instrument requirements. The findinds include: 1. The laboratory performed hematology tests by Sysmex KX21N instrument since February 25, 2024. 2. Review of the hematology written procedure manual showed that no information regarding the following requirements for the Sysmex KX21N system were included: a. requirements for patient preparation, specimen collection, storage, preservation, transportation, processing and referral criteria for specimen acceptability and rejection. b. normal values c. limitations in the test methodoly, including interfering substances d. pertinent literature references e. criteria to determine acceptable control results f. quality control procedures 3. The last revision of the hematology written procedure manual was performed on year 2019. 4. The laboratory technical supervisor confirmed during interview on December 5, 2024 at 12:03 pm, that the laboratory did not have an updated hematology written procedure manual.
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 quality control records review, procedure manual, and laboratory technical supervisor interview on December 5, 2024 at 9:26 am, it was determined that the laboratory failed to monitor and document the laboratory's room temperature and relative humidity from December 1 to December 5, 2024. The findings include: 1. The laboratory establishes in the procedure manual to monitor and document the room temperature and relative humidity daily. 2. The laboratory quality control records showed that the laboratory did not monitor and document the daily the room temperature and relative humidity of the laboratory from December 1 to December 5,

	2024. 3. The laboratory technical supervisor confirmed on December 5, 2024 at 9:31 am, that the laboratory did not monitor and document the room temperature, and relative humidity of the laboratory on the dates previously mentioned.
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: A. Hematology Based on hematology and quality control records review and laboratory technical supervisor interview on December 5, 2024 at 12:32 pm, it was determined that the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 997 Complete Blood Count (CBC) patient samples from November 21, 2024 to December 5, 2024. The findings include: 1. The laboratory uses A-check control material on the Sysmex KX21N instrument to perform hematology CBC patient's samples. 2. The hematology quality control records reviewed on December 5, 2024 at 12:32 pm, from November 21, 2024 to December 5, 2024, showed that there was no evaluation of the manufacturer's stated values for the current lot number 4303 prior to place it in routine use on November 21, 2024. 3. The laboratory general supervisor stated on December 5, 2024 at 12:32 pm, that no evaluations of the current lot of control material were performed prior to place it in routine use. 4. The laboratory tecnical supervisor confirmed on December 5, 2024 at 12:36 pm that the laboratory failed to evaluate the stated value of the new lot of control materials for Complete Blood Count (CBC) tests performed by the Sysmex KX21N hematology system when they processed and reported 997 hematology CBC patient samples from November 21, 2024 to December 5, 2024. B. Urinalysis Based on urinalysis quality control records review and laboratory technical supervisor interview on December 5, 2024 at 1:20 pm, it was determined that the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 50 patient samples from June 1, 2024 to December 5, 2024. The findings include: 1. The laboratory performs urinalysis tests with the Sysmex Clinitek 50 system and uses Thermo Scientific MAS UA control material. 2. The urinalysis quality control records reviewed on December 5, 2024 at 1:20 pm, from June 1, 2024 to December 5, 2024, showed that there was no evaluation of the manufacturer's stated values for the current lot number UB152601M prior to place it in routine use on June 1, 2024. 3. The laboratory general supervisor stated on December 5, 2024 at 1:20 pm, that no evaluations of the current lot of control material were performed prior to place it in routine use. 4. The laboratory tecnical supervisor confirmed on December 5, 2024 at 1:25 pm that the laboratory failed to evaluate the stated value of the new lot of control materials for urinalysis

	tests performed by the Sysmex Clinitek 50 system, when they processed and reported 50 patient samples from June 1, 2024 to December 5, 2024.
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: A. Hematology Based on visual inspection of the hematology control material in use, quality control records, manufacturer's instructions, and interview with the laboratory technical supervisor on December 5, 2024 at 8:45 am, it was determined that the laboratory failed to document the reagent's opened expiration dates of hematology control material in use every time they opened a new control material, when the laboratory processed and reported 8,600 Complete Blood Count (CBC) patient samples from February 25, 2024 to December 5, 2024. The findings include: 1. The laboratory performs hematology CBC tests with the Sysmex KX21N hematology system since February 25, 2024. 2. The manufacturer's instructions of the Sysmex hematology control material state that: unopened control vials can be used until expiration date on the label of the vial, if stored at 2-8 C opened and recapped vials and vials whose caps have been pierced, will retain stability for 14 days if stored at 2-8 C after being re-capped. 3. The visual inspection of the hematology control material in use, and hematology quality control records on December 5, 2024 at 8:45 am, showed that the laboratory did not document the opened expiration date of the hematology control material from February 25, 2024 to December 5, 2024. 4. The laboratory technical supervisor confirmed on December 5, 2024 at 8:50 am, that the laboratory failed to document the expiration date of the hematology control material that were in use, when the laboratory processed and reported 8,600 CBC patient samples from February 25, 2024 to December 5, 2024. B.Urinalysis Based on visual inspection of the urinalysis control material in use, quality control records, manufacturer's instructions, and interview with the laboratory technical supervisor on December 5, 2024 at 8:47 am, it was determined that the laboratory failed to document the reagent's opened expiration dates of urinalysis control material in use every time they opened a new control material, when the laboratory processed and reported 6,076 urinalysis patient samples from January 1, 2023 to December 5, 2024. The findings include: 1. The laboratory performs urinalysis tests with the Sysmex Clinitek 50 system and uses Thermo Scientific MAS UA control material. 2. The manufacturer's instructions of the urinalysis Thermo Scientific MAS UA control material state that unopened vials are stable until the expiration date on the label if stored at 2-8 C, once opened vials of control are stable for 6 weeks when stored tightly capped at room temperature at 18-25 C or 3 months refrigerated at 2-8 C. 3. The visual inspection of the urinalysis control material in use, and urinalysis quality control records on December 5, 2024 at 8:47 am, showed that the laboratory did not document the opened expiration date of the urinalysis control material from January 1, 2023 to December 5, 2024. 4. The laboratory technical supervisor confirmed on December 5, 2024 at 8:52 am, that the laboratory failed to document the expiration date of the urinalysis control material that was in use every time they opened a new control material, when they processed 6,076 patient samples from January 1, 2023 to December 5, 2024. C. Endocrinology Based on endocrinology Human chorionic

	gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory technical supervisor interview on December 5, 2024 at 02:19 pm, it was determined that the laboratory failed to follow manufacturer's instructions to document the external and internal control each day of testing when processing hCG samples. The findings include: 1. The laboratory performed endocrinology (hCG) human chorionic gonadotropin by Aimstep Combo Pregnancy kit. 2. Review of the manufacturer's instructions on December 5, 2024 at 02:19 pm showed that the laboratory must monitor and document each day of testing the external controls and internal control to ensure the validity of the hCG test performed. 3. The hCG test worksheet records showed on December 5, 2024 at 02:19 pm, that the laboratory did not document the observed results of the external and internal control each day of testing when processing hCG samples. 4. The laboratory processed and reported 28 hCG patient samples from January 1, 2024 to December 5, 2024. 5. The laboratory director confirmed on December 5, 2024 at 02:29 pm, that the laboratory did not monitor and document the extermal and internal control each day of testing when processing endocrinology hCG samples.
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, urinalysis and endocrinology quality control records review (years 2023 and 2024), and laboratory supervisor interview on December 5, 2024 at 02:29 pm., it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.
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, urinalysis, and endocrinology quality control records review, it was determined that the laboratory director did not ensure that quality control procedures related to CBC, urinalysis and hCG quality control procedures were performed as established by the manufacturer's instructions. Refer to D5403, D5413, D5469, and D5479.
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, urinalysis, and endocrinology quality control records review, it was determined that the laboratory technical supervisor failed to fulfill her responsibility to ensure that the laboratory follows quality control procedures as established by the manufacturer's instructions. Refer to D5403, D5413, D5469, and D5479.