Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0886478	08/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Metropolitano	369 Domenech Street, San Juan, 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	A recertification survey on August 26, 2024, Inmediate Jeopardy existed for the following conditions : D5024-42 C.F.R 493.1215 Condition : Hematology D6076-42 C.F.R 493.1441 Condition : Laboratory Director In adittion the laboratory was found out of compliance for the following conditions D5014-42 C.F.R 493.1208 Condition : General Immunology D5020-42 C.F.R 493.1212 Condition : Endocrinology
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the lack of human chorionic gonadotropin (serum hCG), mononucleosis tests, complete blood count (cbc 0 quality control records and interview with the laboratory director on August 26, 2024 at 1:30 P.M., it was determined that the laboratory failed to retain the quality control records for the above mentioned tests for at least two (2) years. The findings include: 1. On August 26, 2024 at 1:30 P.m. , review of records showed that the quality control of the years 2023 and 2024 for the Human chorionic gonadotropin test (serum hCG), mononucleosis and CBC quality control graphs were not available. 2.On August 26, 2024 at 2:00 P.M, the laboratory director confirmed that the quality control for the years 2023 and 2024 were not available.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review (2023-2024) and laboratory director interview on August 26, 2024 at 11:30 AM, it was determined that the laboratory failed to maintain the patient records used to monitor and evaluate the laboratory activities (pre-analytic,and post-analytic systems). The findings include: 1. The laboratory Quality Assessment documentation were reviewed since January 2023. The records showed that the laboratory did not identify the patient test request used to perform the evaluations of the pre-analytic and post analytic system during year 2023 and 2024. 2. The laboratory director stated during interview , that the laboratory established to evaluate patient test request and patient test results each year. 3. The laboratory director confirmed on August 26, 2024 at 11:40 A.M. , that the laboratory did not identify the patient test records used to perform the Quality Assessment evaluations.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Infectious Monucleosis (IM) quality control records , patient records review (year 2023-2024) and interview with the laboratory director on August 26, 2024 at 2:00 P.M, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory did not include an external positive and a negative control material each day of IM patient testing. Refer to D5449.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on lack of serum Human Chrorionic Gonadotropin (hCG) test quality control records (years 2023-2024) and interview with the laboratory director on August 26, 2024 at 2:00 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. Refer to D 5449. .
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 lack of hematology quality control records, cell blood count (CBC) calibration verification records and laboratory director interview on August 26, 2024 at 1:30 P.M., it was determined that the laboratory failed to be in compliance with the hematology analytic system requirements since January 2023. Refer to D 5405 (the laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Cell Dyn 1600 hematology system.) Refer to D 5439 (failed to perform Cell Blood Count (CBC) calibration verification procedures), Refer to D5775 (failed to evaluate the relationship of the white blood cells (WBC) differential) Refer to D5789 (fail to retain the quality control records).
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 manufacturer's instructions, hematology quality control records review in 2023-2024 and laboratory director interview at 1:00 P.M.. on August 26, 2024, it was determined that the laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Cell Dyn 1600 hematology system. The findings include: 1. The laboratory uses Cell Dyn 1600 system to perform CBC patient tests. 2. The manufacturer establishes that three levels of control material (low, normal and high) must be included eacth day of testing. 3. Review of CBC control records from January 2023 to December 2023, showed that the laboratory did not include the three levels of controls during the following months: January, February, March (1-22) , April, May, June, July (14-31) and August 2023. 4. The laboratory processed and reported 1,641 Complete Blood Count patient's samples in 2023. 5. Review of CBC control records from January 2024 to August 2024, showed that the laboratory did not include the three levels of controls during the following months: January, February, March and April (1-6) . available. 6. The laboratory processed and reported 1,251 Complete Blood Count patient's samples since January 2024. 7. The laboratory director confirmed on August 26, 2024 at 1:30 P.M.that the laboratory failed to follow manufacturer's instructions when patien specimens were tested for (CBC) Complete Blood Count by the Cell Dyn 1600 instrument.
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 tests (CBC) calibration verification records tests , manufacturer's instructions records reviewed (2023-2024) and laboratory director interview on August 26, 2024 at 10:00 AM, it was determined that the laboratory failed to perform, at least every 6 months, the calibration verification procedures when processed and reported 1, 641 out of 1,641 patients specimens by the Cell Dyn 1600 system . The findings include: 1. The manufacturer instructed the laboratory to perform calibration verification procedures semi annually. 2. On August 26, 2024 at 10:00 AM, the calibration verification records reviewed showed that the laboratory did not perform, at least every 6 months, the calibration verification procedures for the Cell Blood Count (CBC) during year 2023. The calibration verification procedure was performed on 4/17/24. 2. The laboratory director stated on August 26, 2024 at 10:20 A.M. that the calibration verification was performed in 2023, however, no evidence were available during the survey. 3. The laboratory processed and reported 1,641 patients' specimens tests by the Cell Dyn 1600 system in year 2023.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on lack of Infectious Mononucleosis test (IM) quality control records (2023-2024) and interview with the laboratory director on August 26, 2024 at 12:00 P. M, , it was determined that the laboratory did not include a positive and a negative control material, each day, of IM patient testing. The laboratory processed and reported 22 out of 22 patient sample since January 2023. The findings include: a. The laboratory uses the Color Mono II Test (ASI) reagent kit to perform patient IM test. b. On August 26, 2024 at 12:00 P.M, the IM quality control records were requested. The quality control record of IM were not available. c. The laboratory director confirmed on August 26, 2024 at 12:10 P.M, that the laboratory did not have any quality control records for the patient's tested since January 2023. d. The laboratory processed and reported 22 IM patients tests since January 2023. 2. Based on lack of human chorionic gonadotropin (hCG) quality control records and interview with the

	laboratory director on August 26, 2024 at 12:15 P.M, it was determined that the laboratory did not include an external positive and a negative control material, each day, of hCG patient's testing. The laboratory processed and reported 29 out of 29 patient's sample since January 2023 . The findings include: a. The laboratory uses the Aim Step reagent kit to perform patient for pregnancy test. b. On August 26, 2024 at 12:20 P.M, the hCG quality control records were requested. The quality control record of hCG test were not available. c. The laboratory director confirmed on August 26, 2024 at 12:20 P.M, that the laboratory did not have any quality control records for the patient's tested since January 2023. d. The laboratory processed and reported 29 hCG patients tests since January 2023.
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 lack of CBC tests Levy - Jennings graphs from years 2023-2024, review of quality control prints out (year 2023-2024), laboratory information system and interview with the laboratory director on August 26, 2024 at 1:00 P.M., it was found that the laboratory did not evaluate nor define the statistical values of any of the all the lot numbers of the commercial control material used by the Cell Dyn 1600 instrument since year 2023. The findings include: 1. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used since year 2023. 2. The laboratory director stated on August 26, 2024 at 1:10 P.M. that for year 2023 and 2024 the laboratory did not have available the evaluations of the control results to detect any outliers, shifts or trends in control values 3.The laboratory information system showed that the laboratory performed 1,641 (year 2023) and 1,251 (from January to July 2024) patient samples for CBC tests.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on the lack of comparison test results records on white blood cells (WBC), year 2023 and 2024, and interview with the laboratory director on August 26, 2024 at 10: 02 AM; it was determined that the laboratory failed to evaluated twice a year the relationship of the WBC differential results between the manual method and the Cell Dyn 1600 system since January 2023. The findings include: 1. The laboratory performed WBC differential results by two method: manual examination and by the Cell Dyn 1600 system. 2. On August 26, 2024 at 10:02 AM the evaluation of the WBC differential was requested to the laboratory director. No evaluation was available since January 2023. 3. The laboratory director confirmed on August 26, 2024 at 10:10 AM the laboratory did not evaluated , twice a year, the relationship of the WBC differential results between the manual method and the Cell Dyn system since January 2023.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on testing records review of endocrinology tests (hCG) and general immunology and interview with the general supervisor at 10:50 AM on 03/16/2016, it was determined that the laboratory failed to maintain and include the positive identification of the patients specimen and the time of specimen receipt into the laboratory for serum pregnancy and IM tests. The findings include: 1. The 100 % of testing records review showed that the laboratory did not include the positive identification of the patients specimen and the time of specimen receipt in the following testing records: serum pregnancy and IM test . The laboratory include the patient's name and last name as identification in those testing records since 2023. 2. . Since January 2023 , the laboratory processed and reported 29 out of 29 patients specimens for pregnancy test. 4. Since January 2024, the laboratory processed and reported 22 out of 22 patients specimens for IM tests. .
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on the lack of human chorionic gonadotropin (hCG), IM , patient testing records, for years 2023 and 2024, and interview with the laboratory director on August 26, 2024 at 12:40 P.M., it was determined that the laboratory failed to retained the patient testing records that showing reagent kits lot number, expiration dates. The finding included: 1. On August 26, 2024 at 12:40 P.M., the patient testing records for

	human chorionic gonadotropin (hCG), IM were requested by the surveyor. The laboratory director stated , that the patient testing records were not available. The laboratory working areas were observed and no documentation was found.
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: Based on quality assessment (QA) records review (year 2023-2024) , QA procedure manual review and interview with the laboratory director interview on August 26, 2024 at 10:30 A.M., it was determined that the laboratory failed to have policies to monitor and evaluate the following requirements for post analytic systems: turn around test (TAT) . The findings include: 1. Review of the laboratory QA program for year 2023 and 2024 showed that the laboratory did not evaluate the laboratory turn around time since year 2023. 2. Review of the quality assessment program showed that the laboratory did not have policies to evaluate the TAT post analytic system . (review on August 26, 2024 at 10:40 A.M) 3. The laboratory director stated on August 26, 2024 at 10:45 A.M that the evaluations of TAT were not performed.
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 lack of quality control records and lack of quality assessment (year 2023-20243) and laboratory director interview on August 26, 2024, at 2:00 P.M., 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 D6093 and D6094.
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 lack of the hematology (CBC tests) , hCG, and IM quality control records review (year 2023 and 2024), lack of the patients worksheet record and interview with the laboratory director on August 26, 2024 at 1:30 PM; it was determined that the laboratory director failed to ensure the compliance with the analytic requirements. Refer to D5405, D5439, D5449, D5469, D5775, D5787 and D5789.

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 (QA) records review (year 2023-2024) and laboratory director interview on August 26, 2024 at 1:30 P.M.., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records (2023-2024) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory postanalytic systems. (review on August 26, 2024 at 10: 00 A.M.) 2. The laboratory director confirmed on August 26, 2024 at 1:50 P.M. , that failed to evaluate the requirements for laboratory postanalytic systems. Refer to D5891.