Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0682233	12/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Rex	Calle 1 A5 Rexville, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clnico Rex, on December 3, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on December 3, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1100 Facility Administration 42 CFR 493.1207 Syphilis Serology 42 CFR 493.1211 Urinalysis 42 CFR 493.1212 Endocrinology 42 CFR 493.1215 Hematology 42 CFR 493.1250 Analytic Systems 42 CFR 493.1441 Laboratory Director
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), and laboratory director interview on December 3, 2025, at 10:07 a.m., it was determined that the laboratory director failed to sign the attestation statements for the proficiency testing events for the years 2024 and 2025. The findings include: 1. The PRPTSP scores were reviewed from February 2024 through September 2025. 2. The laboratory director did not sign the attestation statements for the proficiency testing records from February 2024 through September 2025. 3. The laboratory director confirmed on December 3, 2025, at 11:15 a.m., that she failed to sign the attestation statements for the years 2024 and 2025.
D2127	HEMATOLOGY CFR(s): 493.851(d)

	(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2025), CASPER Report 0155D, the Proficiency Testing Service Program 2025 Schedule, and laboratory director interview on December 3, 2025, at 11:02 a.m., it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the program. The findings include: 1. The PRPTSP scores and CASPER Report 0155D were reviewed for February 2024 through September 2025. 2. The Proficiency Testing Service Program 2025 Schedule showed that the reporting deadline for the second hematology proficiency testing event was July 29, 2025. The laboratory obtained a score of 0% for this second event. 3. The laboratory director confirmed on December 3, 2025, at 11:15 a.m., that the laboratory failed to report the hematology proficiency testing results for the second event within the time frame established by the PRPTSP.
D2128	HEMATOLOGY CFR(s): 493.851(e) (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 Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2024), CASPER Report 0155D, and laboratory director interview on December 3, 2025, at 9:30 a.m., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory result for the hemoglobin analyte in the first proficiency testing event of year 2024. The findings include: 1. The PRPTSP scores and CASPER Report 0155D were reviewed for January 2024 through September 2025. 2. Review of the PRPTSP scores and CASPER Report 0155D showed that the laboratory obtained an unsatisfactory result of 0% for the hemoglobin analyte in the first proficiency testing event of 2024. No remedial or corrective actions were taken or documented. 3. The laboratory director confirmed on December 3, 2025, at 10:07 a.m., that the laboratory failed to take or document corrective action when the unsatisfactory hemoglobin result was obtained.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

	This CONDITION is not met as evidenced by: Based on Quality Assessment records (QA) (year 2024), proficiency testing records (printouts for years 2024 - 2025), hematology quality control records (years 2024 and January 2025), and laboratory director interview on December 3, 2025, at 1:30 p.m., it was determined that the laboratory failed to retain QA records, proficiency testing report printouts, hematology quality control records, and preventive maintenance service logs for hematology for at least two (2) years. Refer to D3031, D3037, and D3039.
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on the lack of hematology (Complete Blood Count) (CBC) quality control records (years 2024 and January 2025) and interview with the laboratory director on December 3, 2025, at 12:55 p.m., it was determined that the laboratory failed to retain the quality control records for the CBC testing for at least two (2) years, when processed and reported 949 out of 949 CBC patient samples from January 1, 2024, to January 14, 2025. The findings include: 1. The hematology quality control was requested. A facility tour was conducted, and no evidence of quality control records for CBC testing was found. 2. The laboratory director stated that quality control records for hematology for the years 2024 and January 2025 were not available. 3. The laboratory director confirmed on December 3, 2025, at 10:07 a.m., that CBC quality control records for the years 2024 and January 2025 were not available and stated that the Coulter JT quality control system is not linked to the Laboratory Information System (LIS). 4. The laboratory processed and reported 949 out of 949 CBC patient samples from January 1, 2024, to January 14, 2025.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (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 review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025) and laboratory director interview on December 3, 2025, at 10:07 a.m., it was determined that the laboratory failed to retain proficiency testing (PT) records for at least two years, as required. The findings include: 1. The PRPTSP score for February 2024 through September 2025 were reviewed. 2. The laboratory did not have available documentation (reported results printouts) for the hematology proficiency testing events performed on the Coulter JT analyzer for the year 2024 and the first testing event of year 2025. 3. The laboratory director confirmed on December

	3, 2025, at 11:15 a.m., that the laboratory did not have available PT printout results for the year 2024 and stated that the Coulter JT analyzer printer had transmission problems.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) (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 and laboratory director interview on December 3, 2025, at 12:00 p.m., it was determined that the laboratory did not retain or perform the required evaluations of the QA program to monitor and evaluate laboratory activities (general system, pre-analytic, analytic and post-analytic systems) for the year 2024. The findings include: 1. The QA records for the year 2024 were requested. The available QA documentation showed that the laboratory did not perform the required evaluation of the established QA program for year 2024. 2. The laboratory director confirmed on December 3, 2025, at 12:15 p.m., that the laboratory did not evaluate or document the established QA program in the year 2024.
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, 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 the syphilis serology quality control records (years 2024-2025), the manufacturer's instructions, and interview with the testing personnel on December 3, 2025, at 1:50 p.m., it was determined that the laboratory failed to meet the requirements in the subspecialty of Syphilis Serology. The findings include: 1. The laboratory did not include weakly reactive control material, each day of Rapid Plasma Reagin (RPR) patient testing. Refer to D5411 (B). 2. The laboratory did not follow the manufacturer's instructions related to the needle wash. Refer to D5411 (C). 3. The laboratory failed to follow the manufacturer's instructions regarding the established temperature range. Refer to D5413.
D5018	URINALYSIS CFR(s): 493.1211 If the laboratory provides services in the subspecialty of Urinalysis, 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 the lack of urinalysis quality control records (years 2024-2025) and interview with the testing personnel on December 3, 2025, at 12:50 p.m., it was determined that the laboratory failed to ensure compliance with the analytic system

	requirements in the subspecialty of urinalysis. The findings include: 1. The laboratory failed to include microscopic quality control material each day of patient testing. Refer to D5449(B).
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 Human Chorionic Gonadotropin (hCG) quality control records review (years 2024 - 2025) and interview with the testing personnel on December 3, 2025, at 2:30 p.m., it was determined that the laboratory failed to ensure compliance with the analytic system requirements in the subspecialty of endocrinology. The findings include: 1. The laboratory did not include external positive and negative control material, each day of patient testing. Refer to D5449 (A).
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 and laboratory director interview on December 3, 2025, at 1:30 p.m., it was determined that the laboratory failed to ensure compliance with the hematology analytic system requirements in the year 2024 and January 2025. The findings include: 1. The laboratory failed to follow manufacturer's instructions when testing patient specimens for (CBC) Complete Blood Count using the Coulter Analyzer. Refer to D5411 (A). 2. The laboratory failed to perform the annual PM required by the manufacturer for the Coulter JT Analyzer. Refer to D5429. 3. The laboratory failed to evaluate or define the statistical values of any of the lot numbers of the commercial control materials used by the Couter JT Analyzer. Refer to D5469. 4. The laboratory failed to evaluate the relationship of the white blood cells (WBC) differential. Refer to D5775.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review (year2025) and laboratory director interview on December 3, 2025, at 9:30 a.m., it was determined that the laboratory failed to follow the established schedule for competence evaluation for the clinical consultant. The

	findings include: 1. The laboratory's written policy for personnel competence procedures states that competence evaluations must be performed, annually. 2. Personal records review showed that the last competence evaluation for the clinical consultant was performed on October 24, 2024. 3. The laboratory director confirmed on December 3, 2025, at 9:40 a.m., that the competence evaluation for the clinical consultant was not performed in year 2025 as required by the laboratory's annual schedule.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) records and laboratory director interview on December 3, 2025, at 12:00 p.m., it was determined that the laboratory failed to evaluate the QA program and monitor the General Laboratory system for the year 2024. The findings include: 1.The QA records for the year 2024 were requested. 2. The laboratory did not evaluate or monitor the required General Laboratory System requirement: patient confidentiality, specimen identification and integrity, complaint investigation, communication, personnel competency, and proficiency testing evaluation for the year 2024. 3. The laboratory director confirmed on December 3, 2025, at 12:15 p.m., that the QA General Laboratory System activity records were not available for review.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) records and laboratory director interview on December 3, 2025, at 12:05 p.m., it was determined that the laboratory failed to evaluate the QA program and monitor the required pre analytic systems for the year 2024. The findings include: 1. The QA records for the year 2024 were requested. 2. The laboratory did not evaluate or monitor the required pre-analytic system: patient test requests, specimen submission and handling, and specimen referral for the year 2024. 3. The laboratory director confirmed on December 3, 2025, at 12:15 p.m., that the QA Pre-Analytic system activities records were not available for review.
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 the quality control (QC) records review(year 2024-2025) and laboratory director interview on December 3, 2025, at 12:05 p.m., it was determined that the laboratory failed to meet requirements for analytic systems. Refer to D5012, D5018, D5020 , D5024 and D5435.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on the manufacturer's instructions, review of the hematology quality control (QC) records (years 2024-2025), and laboratory director interview on December 3, 2025, at 12:05 p.m., it was determined that the laboratory failed to follow manufacturer's instructions when patient specimens were processed and reported for Complete Blood Count (CBC) testing using the Coulter JT hematology analyzer. The laboratory processed and reported 949 out of 949 CBC patient samples from January 1, 2024, to January 14, 2025. The findings include: 1. The laboratory used Coulter JT hematology analyzer to perform CBC patient testing. 2. The manufacturer's instructions require that three levels of control material (low, normal and high) must be included each day of testing. 3. The hematology QC records were requested and no evidence of QC records for CBC testing was provided by the laboratory. 4. The laboratory did not include the three levels of control during the year 2024 and January 2025. 5. The laboratory director confirmed on December 3, 2025, at 10:07 a.m., that CBC quality control records for the years 2024 and January 2025 were not available. 6. The laboratory processed and reported 949 out of 949 CBC patient samples from January 1, 2024, to January 14, 2025. B. Based on review of the rapid plasma reagin (RPR) quality control (QC) records (years 2024-2025), Aim RPR manufacturer's test system insert, and laboratory testing personnel interview on December 3, 2025,at 1:55 p.m., it was determined that the laboratory did not include a weakly reactive control each day of patient testing, when 161 out of 161 syphilis serology tests were processed and reported from March 23, 2024 to December 2, 2025. The findings include: 1. The laboratory uses the Aim RPR test method to perform syphilis serology testing. 2. Review of the manufacturer's test system insert showed the following requirements: a. Reagent: the kit contains the following reagents a reactive control, weakly reactive control, and non-reactive controls. b. Quality Control: When testing with a negative control, no aggregation should be observed. When testing with a weekly reactive control, slight aggregation should be observed. When testing with reactive control, medium to large aggregates should be observed. When these reactions are found, this will indicate proper procedural technique, specimen volume, and test performance. 3. Review of the RPR QC records showed that the laboratory did not include the weakly reactive control each day of patient testing, when

	processed and reported 161 out of 161 patient samples from March 23, 2024, to December 2, 2025. 4. The laboratory director confirmed on December 3, 2025, at 2:18 p.m., that the laboratory performed QC only the reactive and non-reactive control material each day of patient testing. C. Based on review of the rapid plasma reagin (RPR) quality control (years 2024-2025), Aim RPR method manufacturer's instructions, and laboratory director interview, on December 3, 2025, at 2:15 p.m., it was determined that the laboratory failed to follow the manufacturer's instructions related to the needle wash for syphilis serology testing, when 161 out of 161 patient specimens were tested from March 23, 2024, to December 2, 2025. The findings include: 1.The laboratory uses the Aim RPR method to perform syphilis serology testing. 2. Review of the Aim RPR test manufacturer's instructions showed that the needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. 3. Review of the syphilis serology quality control records showed that the laboratory did not perform or document the required needle cleaning when processed and reported 161 out of 161 RPR patient specimens from March 3, 2024, December 2, 2025. 4. The laboratory director confirmed during interview on December 3, 2025, at 2:20 p.m., that the laboratory did not follow the manufacturer's instructions for needle cleaning.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the syphilis serology manufacturer's instructions, the quality control records (years 2024-2025), and interview with the laboratory director on December 3, 2025, at 2:05 p.m., it was determined that the laboratory failed to perform rapid plasma reagin (RPR) testing according to the manufacturer's required processing temperature. The laboratory processed and reported 161 out of 161 syphilis patient samples outside the specified temperature range. The findings include: 1. The manufacturer's instructions require that RPR testing be performed at room temperature between 20 C and 30 C. 2. Review of syphilis serology quality control records from March 23, 2024, to December 2, 2025, showed that the laboratory processed and reported 161 out of 161 RPR patient testing at 37C. 3. The laboratory director confirmed on December 3, 2025, at 2:25 p.m., that the laboratory performed RPR testing above the temperature range established by the manufacturer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 the manufacturer's specifications, review of the preventive maintenance (PM) records (year 2024), and interview with the laboratory director on December 3, 2025, at 12:18 p.m., it was determined that the laboratory failed to perform the annual PM required by the manufacturer for the Coulter JT analyzer. The laboratory processed and reported 949 out of 949 Complete blood cell (CBC) patient testing from January 1, 2024, to January 14, 2025. . The findings include: 1. The laboratory used the Coulter JT analyzer to perform CBC patient testing. 2. The manufacturer's specifications stated that the PM must be performed annually. 3. Review of the PM records showed that the laboratory did not perform the required annual PM in the year 2024. The last documented PM was completed in December 2023. 4. The laboratory processed and reported 949 out of 949 Complete blood cell (CBC) patient testing from January 1, 2024, to January 14, 2025. 5. The laboratory director confirmed on December 3, 2025, at 12:45 p.m., that the laboratory did not perform the annual PM for the Coulter JT analyzer in the year 2024.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the lack of laboratory annual preventive maintenance records (years 2024-2025), observation of the equipment certification labeling, and laboratory director interview on December 3, 2025, at 11:45 a.m., it was determined that the laboratory failed to perform the peripheral equipment function check evaluation. The findings include: 1. The laboratory did not have annual preventive maintenance records available for review. Observation of the equipment labeling showed that the last annual certifications for the microscope, centrifuge, pipettes, blood mixer, and rotator (speed and circumference) were performed in August 2023. 2. The laboratory director confirmed on December 3, 2025, at 11:50 a.m., that the laboratory had not performed the required equipment certification since August 2023.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: A. Based on the human chorionic gonadotropin (hCG) quality control records and the interview with laboratory director on December 3, 2025, at 2:30 p.m., it was determined that the laboratory did not include external positive and negative control materials each day of hCG patient testing. The laboratory processed and reported 47 out of 47 patient samples from Abril 16, 2024, to November 28, 2025. The findings include: 1. The laboratory uses the Aim Step reagent kit to perform hCG patient testing. 2.. The hCG quality control records were requested. Reviews of the hCG

	quality control records showed that the laboratory did not include the external positive and negative control materials each day of patient testing. 3. The laboratory processed and reported 47 out of 47 hCG patient samples from April 16, 2024, to November 28, 2025. 4. The laboratory director confirmed that the laboratory did not include the external positive and negative control materials each day of patient testing. B. Based on review of the urinalysis quality control records and the interview with laboratory director on December 3, 2025, at 12:50 p.m., it was determined that the laboratory did not include or document positive and negative microscopic sediment control materials when 1,740 out of 1,740 patient samples were processed and reported for manual microscopic from January 1, 2024, to September 30, 2025. The findings include: 1. The urinalysis quality control records were requested. Review of the quality control records showed that the laboratory did not perform or document positive and negative control materials for microscopic sediment urinalysis. 2.The laboratory director confirmed on December 3, 2025, at 12:55 p.m., that the laboratory did not perform the quality control for manual microscopic urinalysis examinations. 3.The laboratory processed and reported 1,740 out of 1,740 patient specimens for urinalysis sediment between January 1, 2024, September 30, 2025.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on the lack of Complete blood cell (CBC) Levy - Jennings graphs, review of quality control printout, and interview with the laboratory director on December 3, 2025 at 12:18 p.m., it was determined that the laboratory did not evaluate or define the statistical values of any of the lot numbers of the commercial control materials used by the Couter JT analyzer in the year 2024 and January 2025. The laboratory processed and reported 949 out of 949 Complete blood cell (CBC) patient samples from January 1, 2024, to January 14, 2025. The findings include: 1. The laboratory did not have any statistical data (Levy-Jennings charts, control value means, or control limits) for the control materials used in the year 2024 and January 2025. 2. The laboratory director confirmed that the laboratory did not have evaluations of the control results and January 2025 to detect outliers, shifts, or trends in control values. 3. The laboratory processed and reported 949 out of 949 Complete blood cell (CBC) patient samples from January 1, 2024, to January 14, 2025.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

	This STANDARD is not met as evidenced by: Based on the lack of comparison test results records for white blood cells (WBC) (year 2024), and laboratory director interview on December 3, 2025, at 11:47 a.m., it was determined that the laboratory failed to evaluate twice a year the relationship of the WBC differential results between the manual method and the Coulter JT analyzer since December 2023. The laboratory processed and reported 949 out of 949 Complete blood cell (CBC) patient samples from January 1, 2024, to January 14, 2025. The findings include: 1. The laboratory performed WBC differential testing using two methods: manual examination and the Coulter JT analyzer. 2. The comparison test results for WBC differential were requested. The laboratory had not evaluated twice a year the relationship of WBC differential results between the manual method and the Coulter JT analyzer since December 2023. 3. During the interview on December 3, 2025, at 11:50 a.m., the laboratory director confirmed that no evaluation of WBC differential results was available since December 2023. 4. The laboratory processed and reported 949 out of 949 Complete blood cell (CBC) patient samples from January 1, 2024, to January 14, 2025.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) records and laboratory director interview on December 3, 2025, at 12:08 p.m., it was determined that the laboratory failed to evaluate the QA Program and monitor the required analytic systems for the year 2024. The findings include: 1. The QA records for the year 2024 were requested. 2. The laboratory did not evaluate or monitor the required analytic system: test procedures, accurate and reliable test system performance, equipment and instruments, reagents, materials, and reagent storage conditions, system maintenance and function checks, control procedures, comparison of test result, test records, and corrective actions for the year 2024. 3.The laboratory director confirmed on December 3, 2025, at 12:15 p.m., that the QA Analytic system activity records were not available for review.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 review of the Quality Assessment (QA) records and laboratory director interview on December 3, 2025, at 12:10 p.m., it was determined that the laboratory failed to evaluate the QA Program and monitor the required post analytic systems for the year 2024. The findings include: 1. The QA records for the year 2024 were requested. 2. The laboratory did not evaluate or monitor the required post- analytic

	system: turnaround time and the patient's final test reports for the year 2024. 3. The laboratory director confirmed on December 3, 2025, at 12:15 p.m., that the QA post-analytic system activities records were not available for review.
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 the Quality Control (QC) records and the Quality Assessment (QA) (years 2024-2025), and the laboratory director interview on December 3, 2025, at 3:00 p.m., it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory QC and QA requirements. Refer to D6090, D6091 and D6093.
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) (e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing (PRPTSP) scores (years 2025) , the CASPER Report 0155D, and laboratory director interview on December 3, 2025, at 11:15 a.m., it was determined that the laboratory director failed to ensure submission of the hematology proficiency testing results within the time frame established by the program. Refer to D2127.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing (PRPTSP) scores (year 2024), the CASPER Report 0155D, and laboratory director interview on December 3, 2025, at 11:15 a.m., it was determined that the laboratory director failed to take corrective action when obtained an unsatisfactory score in the first hematology proficiency testing event of the year 2024. Refer to D2128.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 control (years 2024 - 2025) record review, Quality assesmentmet program (year 2024) and interview with the laboratory director on December 3, 2025, at 3:00 p.m., it was determined that the laboratory director failed to ensure the compliance with the analytic requirements. Refer to D5291, D5391, D5400, D5791 and D5891.