Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0682233	12/07/2023
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
D2053	PARASITOLOGY CFR(s): 492.829(d) (1) For any unsatisfactory 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) 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 Program records review and laboratory director interview on December 7, 2023 at 10:00 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained two unsatisfactory testing event scores (second and third event of year 2022) in parasitology. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since January 2022 to November 2023. 2. Review of Proficiency Testing records on December 7, 2023 at 9:43 AM, showed that the laboratory obtained unsatisfactory results of 30 % percent in the second proficiency testing event and 70% in the third proficiency testing event of Parasitology Concentrations preparations tests in the year 2022. No remedial actions were taken nor document. 3. The laboratory director confirmed on December 7, 2023 at 10:00 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the parasitology specialty.
D2128	HEMATOLOGY CFR(s): 493.851(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 Program records review and laboratory director interview on December 7, 2023 at 10:00 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results for hematocrit analyte in the third event of year 2022. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since January 2022 to November 2023. 2. Review of Proficiency Testing records on December 7, 2023 at 9:51 AM, showed that the laboratory obtained an unsatisfactory testing result of the 60% in the third proficiency event of hematocrit analyte in the year 2022. No remedial actions were taken nor document. 3. The laboratory director confirmed on December 7, 2023 at 10:00 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the hematocrit analyte.
D2170	UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(d) (1) For any unsatisfactory 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 unsatisfactory 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 Program records review and laboratory director interview on December 7, 2023 at 10:00 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in coombs indirect test in the second event of year 2023. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since January 2022 to November 2023. 2. Review of Proficiency Testing records on December 7, 2023 at 9:57 AM, showed that the laboratory obtained unsatisfactory result of 60 % percent in the second proficiency testing event of coombs indirect tests in the year 2023. No remedial actions were taken nor document. 3. The laboratory director confirmed on December 7, 2023 at 10:00 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the second proficnecy testing event of coombs indirect in the year 2023.
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). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on lack of Quality Assessment records (QA) , Immunohematology (non-transfusion) (ABO, Rh, indirect coombs), endocrinology , helicobacter pylori, coagulation, general immunology, urinalysis quality control records and laboratory director interview on December 7, 2023 at 2:18 PM, it was determined that the laboratory failed to be in compliance with the retention requirements. Refer to D3031 and D3035. This deficiency was prior cited in the survey performed on March 25, 2022.
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 test (serum hCG), helicobacter pylori, prothrombin time (PT), partial thromboplastin time (PTT), C-reactive protein (CRP), rheumatoid arthritis (RA), mononucleosis, urinalysis and mycoplasma IgM tests quality control records and interview with the laboratory director on December 7, 2023 at 10:52 AM; it was determined that the laboratory failed to retain the quality control of this tests for at least two (2) years. The findings include: 1. On December 7, 2023 at 9:36 AM, during the entrance conference, the laboratory director informed that the records of quality control of the years 2022 and 2023 of the specialties were not available. 2. On December 7, 2023 at 10:40 AM, the quality control records for Human chorionic gonadotropin test (serum hCG), helicobacter pylori, prothrombin time (PT), partial thromboplastin time (PTT), C-reactive protein (CRP), rheumatoid arthritis (RA), mononucleosis, urinalysis and mycoplasma IgM tests were requested by the surveyor. The laboratory director stated again, that the quality control records were not available. The laboratory cabinets were checked and no documentation was found. 3.On December 7, 2023 at 10:52 AM, the laboratory director confirmed that the quality control for the years 2022 and 2023 was not available.
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on the lack ABO group, Rh type and coombs indirect tests quality control

	records, years 2022 and 2023 and interview with the laboratory director on December 7, 2023 at 10:52 AM; it was determined that the laboratory failed to retain the quality control records of those test for at least two (2) years. The findings include: 1. On December 7, 2023 at 9:36 AM, during the entrance conference, the laboratory director informed that the records of quality control of the years 2022 and 2023 of the Immunohematology specialty were not available at the time of inspection. 2. On December 7, 2023 at 10:40 AM, the quality control records for ABO group and Rh type were requested by the surveyor. The laboratory director stated again tthat the quality control records were not available. The laboratory cabinets were checked and no documentation was found. 3.On December 7, 2023 at 10:52 AM, the laboratory director confirmed that the quality control for the years 2022 and 2023 were not available.
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 the lack of Mycoplasma pneumoniae, C-reactive protein, Rheumatoid arthritis and Mononucleosis quality control records and lack of the patient testing records (years 2022-2023) and interview with the laboratory director on December 8, 2023 at 10:52 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory failed to inlcude any control material for the test mentione above, since January 2022. Refer to D5449 (The laboratory did no include any quality control material).
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 and interview with the laboratory director on December 7, 2023 at 10:52 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of Urinalysis. Refer to D 5445 (failed to include quality control material). and D5789 (failed to retain patient testing records).
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 coagulation quality control records, coagulation patients test records and cell blood count (CBC) calibration verification records, it was determined that the laboratory failed to be in compliance with the hematology analytic system requirements since January 2022. Refer to D 5439 (failed to perform Cell Blood Count (CBC) calibration verification procedures), D5547 (failed to include any control material for coagulation test), D5775 (did not include de relationship of the white blood cells (WBC) differential) and D5789 (fail to retain the quality control records).
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the lack of Immunohematology quality control records, patient testing records and interview with the laboratory director on December 7, 2023 at 10:52 AM, it was determined that the laboratory failed to meet the quality control requirements for the subspecialty of Immunohematology. Refer to D5551 (The laboratory did not include quality control material).
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 laboratory competence schedule, personnel file review and interview with the laboratory director on December 7, 2023 at 9:23 AM; it was determined that the laboratory failed to follow the estabiched schedule for the general supervisor competence since April 2022. The findings include: 1. On December 27, 2023 at 9:00 AM the competence schedule was reviewed. The schedule showed that the general supervisor competence must be performed every year. 2. On December 27, 2023 at 9: 23 AM the laboratory director stated that the general supervisor competence was not performed since April 2022. This deficiency was prior cited in the survey performed on March 25, 2022.
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 the lack of Quality Assessment (QA) activities records (year 2023) and laboratory director interview on December 7, 2023 at 10:18 AM, it was determined that laboratory failed to evaluate and monitor the patient confidentialty, specimen identification and integrity, complaint investigation, communication, personnel competency in the General Laboratory system since January 2023. The findings include: 1. On December 7, 2023 at 10:03 AM, the laboratory general system QA 2023 was requested. The general system QA was no available at the time of inspection. 2. The laboratory director confirmed on December 7, 2023 at 10:18 AM that the laboratory failed to evaluate and monitor the patient confidentialty, specimen identification and integrity, complaint investigation, communication, personnel competency in the General Laboratory system since January 2023. This deficiency was prior cited in the survey performed on March 25, 2022.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 the lack of the Quality Assessment (QA) records (year 2023) and laboratory director interview on December 7, 2023 at 10:18 AM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for pre-analytic systems. The findings include: 1. On December 7, 2023 at 10:03 AM, the laboratory pre-analytic systems QA record was requested. The pre-analytic systems QA for the year 2023 was not available at the time of inspection. 2. Since January 2023 the laboratory did not evaluate practices related to: test request, specimen submission and handling, specimen referral. 3. The laboratory director confirmed on December 7, 2023 at 10:18 AM, that the QA for the year 2023 was not available. This deficiency was prior cited in the survey performed on March 25, 2022.
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 the quality control records and laboratory director interview on December 7, 2023 at 2:00 PM, it was determined that the laboratoty failed to meet requirements for analytic systems. Refer to D5014, D5018, D5024 and D5026.
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 the lack of records and laboratory director interview on December 7, 2023 at 12:45 PM, it was determined that the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, voltage, refrigerator and freezer temperatures, centrifuge maintenance, microscope maintenance and the preventive maintenance of the eye wash station since January 2023. The findings include: 1. On December 7, 2023 at 12:00 PM the laboratory maintenance records were requested. The records showed that since January 2023 the laboratory did not monitor nor document the daily the room temperature, relative humidity, voltage, refrigerator and freezer temperatures, centrifuge maintenance, microscope maintenance and the preventive maintenance of the eye wash station. 4. The laboratory director confirmed on December 7, 2023 at 12:45 PM, that the laboratory did not monitor and document the room temperature, relative humidity, voltage, refrigerator and freezer temperatures, centrifuge maintenance, microscope maintenance and the preventive maintenance of the eye wash station since January 2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and interview with the laboratory director on December 7, 2023 at 1:37 PM; it was determined that the laboratory performed one patient ABO Group and Rh type test with expired reagents of anti-D, cells I, cell II, cell A, cell B. The findings include: 1. The laboratory perform ABO Group and Rh type in the immunohematology (non-transfusion) specialty. 2. On December 7, 2023 at 11:00 AM, the reagent anti-D, cells I, cell II, cell A, cell B that were inside the refrigerator were observed. The reagents cells I, cell II, cell A, cell B had an expiration date of November 24, 2023. The Anti D reagent with Lot # 506316 was expired on September 14 2023. 3. On December 7, 2023 at 1:37 PM, the ABO and Rh patient worksheet records were requested. No written records were available. 4. On December 7, 2023 at 1:40 PM the access to the laboratory electronic records was requested to the laboratory director. 5. Review of the electronic records final test reports showed that from September 14, 2023 to December 6, 2023 the laboratory processed one patient sample with expired reagents on December 4, 2023. 6. The laboratory director confirmed on December 7, 2023 at 1:50 PM that expired reagents were used to perform a petient test sample for ABO and Rh.
D5435	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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 lack of laboratory quality control records, daily worksheet maintenance record and laboratory director interview on December 7, 2023 at 12:45 PM, it was determined that the laboratory failed to monitor and document the laboratory maintenance of centrifuge maintenance, rotator speed and circumference since January 2023. (used for syphilis serology tests) The findings include: 1. The laboratory daily worksheet maintenance records were reviewed on December 7, 2023 at 12:00 PM and showed that the laboratory must document the rotatos speed, circunference and centrifuge maintenance daily. 2. Since January 2023 the laboratory did not monitor and document daily the rotator speed and circumference and centrifuge maintenance. 4. The laboratory director confirmed on December 7, 2023 at 12:45 PM, that the laboratory did not monitor and document daily the rotator speed and circumference and centrifuge maintenance.
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 reviewe and laboratory director interview on December 7, 2023 at 10:48 AM, it was determined that the laboratory

	failed to perform, at least every 6 months, the calibration verification procedures for the Cell Blood Count (CBC) test processed by the Coulter JT, Beckman Coulter system. The findings include: 1. On December 7, 2023 at 10:40 AM, the quality control records was reviewed and 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 last calibration verification procedure was performed on 10/14/2022. 2. The laboratory director confirmed on December 7, 2023 at 10:48 AM, that the laboratory only performed the calibration verification procedures for the CBC test on 10/14/2022. 3. The laboratory processed and reported 1,418out of 1,418 patients specimens tests by the Coulter JT, Beckman Coulter system from January 2023 to November 2023.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Urinalysis quality control records review and interview with the laboratory director on December 7, 2023 at 2:18 PM; it was determined that the laboratory did not include or document any negative microscopic sediment control material when 1,176 patient's were process and reported under the microcope since January 2022. The findings include: 1.. On December 7, 2023 at 1:53 PM, the quality control records of urinalysis were requested. The quality control of urinalysis were not available. b. The laboratory director state on December 7, 2023 at 2:18 PM that no microcopy control was available since January 2022 when 1,176 patient's were processed and reported.
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 Mycoplasma pneumoniae IgM quality control records and interviw with the laboratory director on December 7, 2023 at 2:18 PM, it was determined that the laboratory did not include an external positive and negative control material, each day, of Mycoplasma pneumoniae IgM patient testing. The laboratory processed and reported 58 out of 58 patient sample's since January 2022. The findings include: a. The laboratory uses the Immunocard reagent kit by Meridian

to perform patient Mycoplasma pneumoniae IgM test. b. On December 7, 2023 at 12: 30 PM the Mycoplasma pneumoniae IgM quality control records were requested. The quality control record of Mycoplasma pneumoniae IgM were not available. c. The laboratory director confirmed on December 7, 2023 at 2:18 PM, that the laboratory did not have any quality control records for the patient's tested since January 2022. She confirmed that 58 patient's samples were processed since January 2022. 2. Based on lack of Mononucleosis quality control records and interview with the laboratory director on December 7, 2023 at 2:18 PM, it was determined that the laboratory did not include positive and negative control material, each day, of Mononucleosis (Mono) patient testing. The laboratory processed and reported one patient sample since January 2022. The findings include: a. The laboratory uses the ASI reagent kit to perform patient Mono test. b. On December 7, 2023 at 12:30 PM the Mono quality control record were requested. The quality control record of Mono were not available. c. The laboratory director confirmed on December 7, 2023 at 2:18 PM., that the laboratory did not have any quality control records for the patient's tested since January 2022. She confirmed that one patient sample was processed since January 2022. 3. Based on lack of C-Reactive Protein (CRP) quality control records and interview with the laboratory director on December 7, 2023 at 2:18 PM, it was determined that the laboratory did not include positive and negative control material, each day, of CRP patient testing. The laboratory processed and reported 49 out of 49 patient sample's since January 2022. The findings include: a. The laboratory uses the ASI reagent kit to perform patient CRP test. b. On December 7, 2023 at 12:30 PM the CRP quality control record were requested. The quality control record of CRP were not available. c. The laboratory director confirmed on December 7, 2023 at 2:18 PM., that the laboratory did not have any quality control records for the patient's tested since January 2022. She confirmed that 49 out of 49 patient's sample was processed since January 2022. 4. Based on lack of Rehumatoid arthritis (RA) quality control records and interview with the laboratory director on December 7, 2023 at 2:18 PM, it was determined that the laboratory did not include positive and negative control material, each day, of RA patient testing. The laboratory processed and reported 24 out of 24 patient sample since January 2022. The findings include: a. The laboratory uses the ASI reagent kit to perform patient RA test. b. On December 7, 2023 at 12:30 PM, the RA quality control record were requested. The quality control record of RA were not available. c. The laboratory director confirmed on December 7, 2023 at 2:18 PM., that the laboratory did not have any quality control records for the patient's tested since January 2022. She confirmed that 24 out of 24 patient's sample were processed since January 2022.. 5. Based on lack of Helicobacter pylori quality control records and interview with the laboratory director on December 7, 2023 at 2:18 PM, it was determined that the laboratory did not include positive and negative control material, each day, of Helicobacter pylori patient testing. The laboratory processed and reported two out of two patient sample since January 2022. The findings include: a. The laboratory uses the Immunocard by Meridian reagent kit to perform patient of Helobacter pylori test. b. On December 7, 2023 at 12:30 PM the Helicobacter pylori quality control record were requested. The quality control record of Helicobacter pylori were not available. c. The laboratory director confirmed on December 7, 2023 at 2:18 PM., that the laboratory did not have any quality control records for the patient's tested since January 2022. She confirmed that two out of two patient's sample were processed since January 2022. 6. Based on lack of human chorionic gonadotropin (hCG) quality control records and interview with the laboratory director on December 7, 2023 at 2:18 PM, it was determined that the laboratory did not include an external positive and negative control material, each day, of hCG patient's testing. The laboratory processed and reported 39 out of 39 patient's sample since January 2022. The findings include: a. The laboratory uses the Aim Step reagent kit to

	perform patient for pregnancy test. b. On December 7, 2023 at 12:30 PM the pregnancy quality control record were requested. The quality control record of pregnancy were not available. c. The laboratory director confirmed on December 7, 2023 at 2:18 PM., that the laboratory did not have any quality control records for the patient's tested since January 2022. She confirmed that 39 out of 39 patient's sample were processed since January 2022.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the lack of coagulation quality control records and interview with the laboratory director on December 7, 2023 at 10:52 AM, it was determined that the laboratory did not verify the normal patients prothrombin time (PT) mean of the Innovin PT reagent prior to report patient's INR (International Normalized ratio) sample. The findings include: 1. The laboratory used the BFT II instrument to perform PT patient's sample. 2. On December 7, 2023 at 10:50 AM the quality control records of coagulation test of years 2022 and 2023 were requested. No quality control records were available since January 2022. 3. The laboratory director confirmed on December 7, 2023 at 10:52 AM that the laboratory fail to verify the PT mean of the Innovin reagent prior to report patient's sample.
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the lack of quality control record of coagulation test and interview with the laboratory director on December 7, 2023 at 2:18 PM, it was determined that the laboratory fail to include two level of control materials prior to perform patient samples testing since January 2022. The laboratory processed and reported 87 out of 87 patient samples for Prothrombin time (PT) and 74 out of 74 Partial thromboplastin time (PTT) patient sample's. The findings include: 1. On December 7, 2023 at 10:52 AM the quality control records for PT and PTT were requested. No quality control were available. 2. On December 7, 2023 at 2:18 PM the laboratory director confirmed that no quality control for PT and PTT were available since January 2022. The laboratory processed and reported 87 out of 87 patient samples for Prothrombin time (PT) and 74 out of 74 Partial thromboplastin time (PTT) patient sample's.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)

	(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on lack of immunohematology quality control records and laboratory director interview on December 7, 2023 at 1:37 PM, it was determined that the laboratory did not document the ABO group, Rh type, and indirect coomb's quality control test results since January 2022. The laboratory processed and reported eight out of eight ABO group and Rh type patient sample's and two out of two inderect coomb's patient samples The findings include: 1. On December 7, 2023 at 11:00 AM, the laboratory immunohematology quality control records were requested. No quality control was available. 2. On December 7, 2023 at 1:50 PM the laboratory director confirmed that the laboratory failed to perform the quality controls of ABO, Rh and indirect coombs since January 2022. The laboratory processed and reported eight out of eight ABO group and Rh type patient sample's and two out of two inderect coomb's patient samples.
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 2022 and 2023, and interview with the laboratory director on December 7, 2023 at 10: 50 AM; it was determined that the laboraotry failed to evaluated twice a year the relationship of the WBC differential results between the manual method and the Coulter JT system since January 2022. The findings include: 1. The laboratory performed WBC differential results by two method: manual examination and by the Coulter JT system. 2. On December 7, 2023, at 10:53 AM the evaluation of the WBC was requested to the laboratory director. No evaluation was available since January 2022. 3. The laboratory director confirmed on December 7, 2023 at 10 :58 AM that the laboratory did not evaluated twice a year the relationship of the WBC differential results between the manual method and the Coulter JT since January 2022.
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), helicobacter pylori, prothrombin time (PT), partial thromboplastin time (PTT), C-reactive protein, rheumatoid arthritis, mononucleosis, urinalysis, and mycoplasma pneumoniae IgM patient testing records, for years 2022 and 2023, and interview with the laboratory director on December 7, 2023 at 2:20 PM; it was determined that the laboratory failed to retained the patient testing records that showing reagent kits lot number, expiration dates and the BFT II instrument printouts. The findings include: 1. On December 7, 2023 at 9:36 AM, during the entrance conference, the laboratory director informed that the patient testing records of the years 2022 and 2023 were not available. 2. On December 7, 2023 at 10:40 AM, the patient testing records for human chorionic gonadotropin (hCG), helicobacter pylori, prothrombin time (PT), partial thromboplastin time (PTT), C-reactive protein, rheumatoid arthritis, mononucleosis, urinalysis, and mycoplasma pneumoniae IgM were requested by the surveyor. The laboratory director state again, that the patient testing records were not available. The laboratory cabinets were checked and no documentation was found.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of the analytic Quality Assessment (QA) records and laboratory director interview on December 7, 2023 at 10:18 AM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for analytic systems. The findings include: a. On December 7, 2023 at 10: 03 AM, the laboratory analytic QA record were requested. No QA records were available. b. Since January 2023 the laboratory did not evaluate practices related to: test procedures, accurate and reliable test system, equipment, instruments, reagents, materials, specimen and reagent storage conditions, system maintenance and function checks, verification of method performance specifications, calibration, control procedures, comparison of test results, test records, corrective ations. c. The laboratory director confirmed on December 7, 2023 at 10:18 AM, that the analytic QA evaluation were not available. This deficiency was prior cited in the survey performed on March 25, 2022.
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 the lack of postanalytic Quality Assessment records (QA) and laboratory director interview on December 7, 2023 at 10:18 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: accuracy of calculated data. The findings include: 1. The Quality Assessment records was requested on December 7, 2023 at 10:03 AM. No postanalytic QA evaluations were available. 2. The laboratory director confirmed on December 7, 2023, at 10:18 AM that the laboratory did not evaluate the accuracy of calculated data since January 22, 2023.
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 and laboratory director interview on December 7, 20223, at 2:30 PM, it was determined that the laboratory director failed to fulfill his responsabilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D6094 and D6093 This deficiency was prior cited in the survey performed on March 25, 2022.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (years 2022-2023) and laboratory director interview on December 7, 2023 at 10:00 A. M, it was determined that the laboratory director failed to evaluate any problems relate to PT performance. Refer to D5053 (The laboratory failed to take and document corrective action when obtaine two consecutive unsatisfactory testing event scores on paratirology specialties), D2128 (The laboratory failed to take and document corrective action when obtaine an unsatisfactory testing event scores on hematocrite analyte).
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 quality control records (year 2022 and 2023), lack of the patients worksheet record and interview with the laboratory director on December 7, 2023 at 2: 30 PM; it was determined that the laboratory director failed to ensure the compliance with the analytic requirements. Refer to D5400
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 lack of the Quality Assesstment (QA) records and interview with the laboatory director on December 7, 2023 at 2:30 PM; it was determined that the laboratory director failed to ensure the compliance with QA requirements year 2023. Refer to D5291, D5391, D5791 and D5891.