Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0707929	01/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Luis Munoz Rivera	Calle Munoz Rivera #21, Vega Alta, 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
D2082	GENERAL IMMUNOLOGY CFR(s): 493.837(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 test scores (submitted by the Puerto Rico Proficiency department) , Casper Report # 155 and 153 year 2022-2023 and laboratory director interview on January 18, 2024 at 9:50 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory result in Rubella test in the second testing event of year 2022. The findings include: 1.During the pre survey activities reports 155, 153 and the Puerto Rico Proficiency test scores were reviewed. The scores showed that the laboratory obtained a 20 % score for Rubella in the second testing event of year 2022. 2. During interview with the laboratoyr director on January 18, 2024 at 9:55 A.M. , the proficiency test scores and remedial action were requested. 3. The laboratory director confirmed on January 18, 2024 at 9:55 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the second proficiency testing event of Rubella in the year 2022 and also confirmed that the Proficiency Testing Program records and results were not available in the laboratory.
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 test scores (submitted by the Puerto Rico Proficiency department) , Casper Report # 155 and 153 year 2022-2023 and laboratory director interview on January 18, 2024 at 9:40 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory result in hematocrit test in the third testing event of year 2022. The findings include: 1.During the pre survey activities reports 155, 153 and the Puerto Rico Proficiency test scores were reviewed. The scores showed that the laboratory obtained a 60 % score for hematocrit in the third testing event of year 2022. 2. During interview with the laboratoyr director on January 18, 2024 at 9:45 A.M. , the proficiency test scores and remedial action were requested. 3. The laboratory director confirmed on January 18, 2024 at 9:45 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the third proficiency testing event of hematocrit in the year 2022 and also confirmed that the Proficiency Testing Program records and results were not available in the laboratory.
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 test scores (submitted by the Puerto Rico Proficiency department) , Casper Report # 155 and 153 year 2022-2023 and laboratory director interview on January 18, 2024 at 10:00 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory result in indirect Coombs test in the second testing event of year 2023. The findings include: 1.During the pre survey activities reports 155, 153 and the Puerto Rico Proficiency test scores were reviewed. The scores showed that the laboratory obtained a 60 % score for indirect Coombs in the second testing event of year 2023. 2. During interview with the laboratoyr director on January 18, 2024 at 10: 10 A.M. , the proficiency test scores and remedial action were requested. 3. The laboratory director confirmed on January 18, 2024 at 10:10 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the second proficiency testing event of indirect Coombs in the year 2023 and also confirmed that the Proficiency Testing Program records and results were not available in the laboratory.

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) , Proficiency testing records, quality control records for : Immunohematology (non-transfusion) (ABO, Rh, indirect Coombs), endocrinology , hematology, coagulation, general immunology, syphilis serology, urinalysis quality control records and laboratory director interview on January 18, 2024 at 12: 15 P.M., it was determined that the laboratory failed to be in compliance with the retention requirements. Refer to D3001, D3031, D3035, D3037 and D3039.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation in the laboratory general testing area , laboratory director interview on January 18, 2024 at 12:20P.M., it was determined that the laboratory failed to ensure that the laboratory space were arranged and in order to provide enough apace for handling, examination and testing of patient samples. The findings include: 1. At 12:20 P.M. the laboratory testing area was observed . The area was crowded with ; letting no spaces for testing or documentation areas. 2. The laboratory director confirmed on January 18, 2024 at 12:25 P.M., that the testing area and reporting area was very crowded with few space to perform the patient samples. 3. The laboratory processed and reported approximately 2,167 patient samples from January 1, 2023 to January 18, 2024.
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), Rubella, prothrombin time (PT), partial thromboplastin time (PTT), C-reactive protein (CRP),

	hematology, rheumatoid arthritis (RA), mononucleosis, urinalysis and mycoplasma IgM tests quality control records and interview with the laboratory director on January 18, 2024 at 10:52 AM; 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 January 18, 2024 at 8:30 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 January 18, 2024 at 10:30 AM, the quality control records for Human chorionic gonadotropin test (serum hCG, prothrombin time (PT), partial thromboplastin time (PTT), C-reactive protein (CRP), rheumatoid arthritis (RA), mononucleosis, urinalysis and mycoplasma IgM tests were , again, requested by the surveyor. The laboratory director stated again that the quality control records were not available. The laboratory work area was checked and no documentation was found. 3.On January 18, 2024 at 11:00 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 January 18, 2024 at 11:00 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 January 18, 2024 at 8:30 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 January 18, 2024 at 11:20 AM, the quality control records for ABO group and Rh type were , again, requested by the surveyor. The laboratory director stated again that the quality control records were not available.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(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 lack of Puerto Rico Proficiency Testing records (2022--2023) and laboratory director interview on January 18, 2024 at 9:00 A.M. , it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were request on January 18, 2024 at 9:00 A.M. 2. The laboratory director stated on January 18, 2024 at 9: 05 A. M. tha the Proficiency Testing records from year 2022-2023 (results reported, test results scores and attestation statements) were not available in the laboratory.
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 lack of Quality Assessment (QA) records (year 2022-2023) and laboratory director interview on January 18, 2024 at 9:45 AM, it was determined that the laboratory failed to maintain the Quality Assessment Program documentaion; used to monitor and evaluate the laboratory activities(general system , pre-analytic, analytic and post-analytic systems) for at least 2 years. The findings include: 1. At 9:45 A.M. the QA program evaluation was requested. The QA Program evaluation was not available. The last documentation dated from December 2021. 2. The laboratory director confirmed on January 18, 2024 at 9:50 A.M., that the laboratory did not have available the Quality Assessment documentation in the laboratory.
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 lack of Syphilis serology quality control records, patient testing records (years 2022-2023) , worksheet notebooks review (March 2022-May 2022) and interview with the laboratory director on January 18, 2024 at 11:40 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of Syphilis Serology since May 17, 2022. The finding includes: 1.On January 18, 2024 at 11:40 A.M, the laboratory worksheet notebook , that included the quality control and patient test record , was reviewed , and showed that the laboratory failed to document any control material nor patient test results since May 17, 2022. 2.On January 18, 2024 at 11:45 A.M, the laboratory director confirmed that the laboratory failed to document the quality control nor the patient test results for this test since year 2022 . Refer to D5405 (The laboratory failed to follow manufacturer's instructions.
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, worksheet notebooks review (March 2022-May 2022) and interview with the laboratory director on January 18, 2024 at 11:50 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of Diagnostic Immunology. The finding includes: 1. The laboratory Diagnostic immunology worksheet notebook were reviewed and showed the following: a.The laboratory failed to include a positive and a negative

	control material for the following tests : C-reactive protein, Rheumatoid arthritis and Mononucleosis since May 2022. b.The laboratory failed to include a positive and a negative control material for the Mycoplasma pneumoniae test since November 2022. 2.On January 18, 2024 at 12:00 P.M, the laboratory director confirmed that the laboratory failed to document the quality control for these tests since year 2022 . Refer to D5449 (The laboratory did not 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 (year 2022-2023) and interview with the laboratory director on January 18, 2024 at 11:30 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, hematology quality control records, cell blood count (CBC) calibration verification records and laboratory director interview on January 18, 2024 at 12:15 P.M., it was determined that the laboratory failed to be in compliance with the hematology analytic system requirements since March 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 (failed to evaluate the relationship of the white blood cells (WBC) differential) and D5789 (fail to retain the quality control records), D5417(the laboratory used sample collection tubes with exceeded expiration date).
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 January 18, 2024 at 12:30 P.M, ,

	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 immunohematology quality control material).
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 2022-2023) and laboratory director interview on January 18, 2024 at 9:45 A.M , it was determined that laboratory failed to evaluate and monitor the patient confidentiality, specimen identification and integrity, complaint investigation, communication, personnel competency in the General Laboratory system since January 2022. The findings include: 1. On January 18, 2024 at 9:45 A..M , the laboratory general system QA 2022-2023 was requested. The general system QA was not available for evaluation. 2. The laboratory director confirmed on January 18, 2024 at 9:47 A.M. that the laboratory QA General System activities records was not available in the laboratory.
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 2022-2023) and laboratory director interview on January 18, 2024 at 9:45 A..M , 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 January 18, 2024 at 9:45 A..M, the laboratory pre-analytic systems QA record was requested. The pre-analytic systems QA since year 2022 was not available at the time of inspection. 2. Since August 2021 the laboratory did not evaluate practices related to: test request, specimen submission and handling, specimen referral. 3. The laboratory director confirmed on January 18, 2024 at 9:45 A..M, that the QA for the year 2022-2023 was not available.
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 (year 2022-2023) and laboratory director interview on January 18, 2024, at 12:30 P.M., it was determined that the laboratory failed to meet requirements for analytic systems. Refer to D5012, D5014, D5018, D5020, D5024 , D5026 and D5026.
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: 1. Based on lack of Rapid Plasma Reagin (RPR) workbook and interview with the laboratory director on January 18, 2024 at 11:50 A.M, it was determined that the laboratory did not include external control material (reactive, weakly reactive and no reactive) , each day, of RPR patient testing. The laboratory processed and reported 124 out of 124 patient sample's since May 2022. The findings include: a. On January 18, 2024 at 11:50 A.M, the RPR quality control records was requested. The laboratory director showed a workbook. The workbook showed that prior to May 2022, the laboratory documented the daily quality control and the patient test results. After May 2022 no quality control nor patient results were documented. b. The patient test results were requested since May 2022 to determine the total number and days of patient testing. The laboratory director inform that she was not able to provide the test results due some kind of problem with the laboratory printer. c. The laboratory director confirmed on January 18, 2024 at 11:52 A.M , that the laboratory did not have any quality control records of RPR tests for the patient's tested since May 2022. She stated that a total of 124 patient samples were tested for RPR since May 2022. The information was obtained by her from the laborator information system (LIS). 2. Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review from January 2022 to November 2022 and interview with the laboratory supervisor on January 18, 2024 at 10:30 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 112 out of 112 patients specimens were tested and reported for of Mycoplasma pneumoniae since March 2022. The findings include: a. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. b. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. b. On January 18, 2024 at 10:30 AM, review of the Mycoplasma pneumoniae testing records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from March 2022 to November 2022. c.The laboratory supervisor confirmed on January 18, 2024 at 10:38 AM, that the laboratory did not monitor nor document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test.
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 (2023) and laboratory director interview on January 18, 2024 , at 11:40 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 January 18, 2024, at 11:45 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. 2. The laboratory director confirmed on January 18, 2024 at 11:45 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 at the laboratory sample collection area, patient samples results review and laboratory director interview on January 18, 2024 at 12:15 P.M., it was determined that the laboratory used sample collection tubes that have exceeded their expiration date. The findings include: 1. On January 18, 2024 at 12:15 P.M. the laboratory sample collection area was observed. 2. The laboratory had one sample collection station. At 12:15 P.M., the sample collection station had in use the following tubes that have exceeded their expiration date: a. Twenty one Buffered Sodium Citrate pale blue top tubes, lot number 3074231, expiration date 12/31/2023 were found. b. Review of patient records showed that two coagulation patients samples (Prothrombin time and Partial thromboplastin time) were perfomed and reported with the expired tubes : id # 218864 (1/3/2024) id # 21886 (1/8/2024 3. The laboratory director confirmed on January 18, 2024 at 12:20 P.M. that the patient samples were collected with expired collection tubes , and the remaning tubes were also expired.
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 annual preventive maintenance records (2022-2023) , obsevation of the equipment certificaction labeling and laboratory director interview on January 18, 2024, at 12:20 PM, it was determined that the laboratory failed to ensure that the laboratory performed the certification of the following equipment : serofuge, microspcope , centrifuge maintenance, rotator speed and circumference since January 2022. The findings include: 1. The laboratory did not have available the annual preventive maintenance records. At 12:20 P.M., observed the labeling of the laboratory equipment and showed that the last annual certification of the following equipment : serofuge, microscope, mixer, rotator and centrifuge were performed on January 2022. 2. The laboratory director stated on January 18, 2024, at 12:25 PM, that the laboratory failed to performed the certification of the equipments since January 2022.
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 calibration vertification, manufacturer's instructions records reviewed (2022-2023) and laboratory director interview on January 18, 2024 at 10: 48 AM, it was determined that the laboratory failed to perform, at least every 6

	months, the calibration verification procedures when processed and reported 794 out of 794 patients specimens tests by the Coulter JT system . The findings include: 1. On January 18, 2024 at 10:50 AM, the calibration vertification 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 1/17/2024. The manufacturer instructed the laboratory to perform calibration verification procedures semi annually. 2. The laboratory director stated on January 18, 2024 at 10:55 A.M. that the calibration verification was performed in 2023, however, no evidence were available during the survey. 3. The laboratory processed and reported 794 out of 794 patients specimens tests by the Coulter JT system from January 2023 to January 18, 2024.
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 interview with the laboratory director on January 18, 2024 at 11:50 A.M, 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 41 out of 41 patient sample's from January 2023 to January 18, 2024. The findings include: a. The laboratory uses the Immunocard reagent kit by Meridian to perform patient Mycoplasma pneumoniae IgM test. b. On January 18, 2024 at 11:50 A.M, 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 January 18, 2024 at 11:52 A.M , that the laboratory did not have any quality control records for the patient's tested from January 2023 to January 18, 2024. 3. Based on lack of C-Reactive Protein (CRP) quality control records and interview with the laboratory director on January 18, 2024 at 11:55 A.M, , 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 28 out of 28 patient sample's from May 16, 2022 to January 18, 2024. The findings include: a. The laboratory uses the ASI reagent kit to perform patient CRP test. b. On January 18, 2024 at 11:55 A.M, the CRP quality control record were requested. The quality control record of CRP were not available. c. The laboratory director confirmed on January 18, 2024 at 11:58 A.M, that the laboratory did not have any quality control records for the patient's tested since May 16, 2022. She confirmed that 28 out of 28 patient's sample was processed from May 16, 2022 to January 18, 2024. 4. Based on lack of Rheumatoid arthritis (RA) quality control records and interview with the laboratory director on January 18, 2024 at 12:05 P.M, , 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 18 out of 18 patient sample from May 16, 2022 to January 18, 2024. The findings include: a. The laboratory uses the ASI reagent kit to perform patient RA test. b. On January 18, 2024 at 12:05 P.M, the RA quality control record were requested. The quality control record of RA were not available. c. The laboratory director confirmed

	on January 18, 2024 at 11:45 A.M, that the laboratory did not have any quality control records for the patient's tested since May 2022. She confirmed that 18 out of 18 patient's sample were processed from May 16, 2022 to January 18, 2024. 5. Based on lack of Rubella quality control records and interview with the laboratory director on January 18, 2024 at 12:10 P.M., it was determined that the laboratory did not include positive and negative control material, each day, of Rubella patient testing. The laboratory processed and reported 13 out of 13 patient sample from January 2023 to January 2024. The findings include: a. On January 18, 2024 at 12:10 P.M, the Rubella quality control record were requested. The quality control record of Rubella were not available. c. The laboratory director confirmed on January 18, 2024 at 12:12 P.M, , that the laboratory did not have any quality control records for the patient's tested since January 2023. The records showed that 13 out of 13 patient's sample were processed from since January 2023. 6. Based on lack of human chorionic gonadotropin (hCG) quality control records and interview with the laboratory director on January 18, 2024 at 12:15 P.M, 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 70 out of 70 patient's sample since January 2023 to January 2024. The findings include: a. The laboratory uses the Aim Step reagent kit to perform patient for pregnancy test. b. On January 18, 2024 at 12:18 P.M, the hCG quality control record were requested. The quality control record of hCG test were not available. c. The laboratory director confirmed on January 18, 2024 at 12:20 P.M, that the laboratory did not have any quality control records for the patient's tested since January 2023. She confirmed that 70 out of 70 patient's sample were processed since January 2023. 7. Based on lack of Urinalysis quality control records review and interview with the laboratory director on January 18, 2024 at 10: 30 A.M; it was determined that the laboratory did not include or document any negative and positive control and negative microscopic sediment control material when 746 out of 746 patient samples were process and reported for manual microscopic from January 2023 to January 2024. The findings include: a. The laboratory used a Clinitek 100 system to perform Urynalisis test. b. On January 18, 2024 at 10:30 AM, the quality control records of urinalysis were requested. The quality control of urinalysis were not available. c. The laboratory director state on January 18, 2024 at 10:35 A.M that negative and positive control and negative microcopic sediment control was available since January 2023 when 746 out of 746 patient's were processed and reported.
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: 1. Based on the lack of coagulation quality control records and interview with the laboratory director on January 18, 2024 at 12:25P.M, it was determined that the laboratory did not verify the normal patients prothrombin time (PT) mean of the Innova PT reagent prior to report patient's INR (International Normalized ratio) sample. The findings include: a. The laboratory used the BFT II instrument to perform PT patient's sample. b. On January 18, 2024 at 12:30 P.M the quality control records

	of coagulation test of years 2022 and 2023 were requested. No quality control records were available since January 2022. c. The laboratory director confirmed on January 18, 2024 at 12:35 P.M., that the laboratory did not have available the documentation of the verification of the PT mean of the Innova reagent perform prior to report patient's sample. 2. Based on the lack of quality control record of coagulation test and interview with the laboratory director on January 18, 2024 at 12:15 P.M, it was determined that the laboratory fail to include two level of control materials prior to perform patient samples testing since March 2022. The laboratory processed and reported 63 out of 63 patient samples for Prothrombin time (PT) and Partial thromboplastin time (PTT) patient sample's. The findings include: a. On January 18, 2024 at 12:15 P.M the quality control records for PT and PTT were requested. No quality control were available. b. On January 18, 2024 at 12:16 P.M the laboratory director confirmed that no quality control for PT and PTT were available since March 2022. The laboratory processed and reported 63 out of 63 patient samples for Prothrombin time (PT) and 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 January 18, 2024 at 11:35 A.M, it was perform not documented 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 13 out of 13 ABO group and Rh type patient sample's and 12 out of 12 indirect coomb's patient samples The findings include: 1. On January 18, 2024 at 11:35 AM, the laboratory immunohematology quality control records were requested. No quality control was available. 2. On January 18, 2024 at 11:40A.M 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 13 out of 13 ABO group and Rh type patient sample's and 12 out of 12 indirect coomb's patient samples 3. On January 18, 2024 at 11:45 AM, the ABO group and Rh type reagents in use were requested by the surveyor. The laboratory director stated that those reagents were shared with the Clinical laboratory Rex (40 D0682233 and were not available in the laboratory.
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 January 18, 2024 at 9:45 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 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 January 18, 2024 at 9:45 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 January 18, 2024 at 9:48 AM 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.
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 the lack of human chorionic gonadotropin (hCG), Rubella, 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 January 18, 2024 at 11:20 AM; 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 January 18, 2024 at 8:30 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 January 18, 2024 at 11:30 A.M, the patient testing records for human chorionic gonadotropin (hCG), Rubella, 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 working area 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 January 18, 2024 at 9:55 A.M. it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for analytic systems. The findings include: 1. On January 18, 2024 at 9: 55 AM, the laboratory analytic QA record were requested. No QA records were available. 2. 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 actions. 3. The laboratory director confirmed on January 18, 2024 at 10:00 AM, that the analytic QA evaluation were not available.
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) , QA records from 2021 review and laboratory director interview on January 18, 2024 at 10:10 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: turn around time and the patient's final test reports. The findings include: 1. The Quality Assessment records was requested on January 18, 2024 at 10: 10 AM. No postanalytic QA evaluations were available. 2. The records showed thta the laboratory did not evaluate the turn around time and the patient's final test reports since 2021. 3. The laboratory director confirmed on January 18, 2024 at 10:10 AM, that the laboratory did not evaluate the turn around time and the patient's final test reports since 2021. No postanalytic QA evaluations were available since 2021.
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 Proficiency testing records, quality control records and lack of quality assessment (year 2022-2023) and laboratory director interview on January 18,2024, at 12:30 PM, 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 D6083, D6091, D6094 and D6093
D6083	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on observation in the laboratory general testing area and interview with the laboratory director on January 18, 2024 at 12:20P.M, it was determined that the laboratory director did ensure that the laboratory (crowded space) were appropriate for specimen testing and handling. Refer to D3001.
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 lack Puerto Rico Proficiency Testing Program records (years 2022-2023) and laboratory director interview on Janaury 18, 2024 at 9:30 A.M., it was determined that the laboratory director failed to evaluate any problems relate to PT performance. Refer to D2082- the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in Rubella test in the second testing event of year 2022. Refer to D2128- the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results for hematocrit analyte in the third testing event of year 2022. Refer to D2170- the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in coombs indirect test in the second testing event of year 2023.
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 January 18, 2024 at 12: 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 Assessment (QA) records and interview with the laboratory director on January 18., 2024 at 12: 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.