Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658298	08/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Risan	Ave Roberto Sanchez Vilella Urb Country Club, Carolina, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the proficiency sample evaluation results, laboratory proficiency sample print out and interview with tha laboratory testing personnel on August 25, 2023 it was determined that the laboratory engaged inter-laboratory communication with other laboratory during the first and second events for the hematology specialty. Refer to D2009, D2013.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Proficiency Testing Program records review (years 2022 and 2023) and

	laboratory testing personnel interview on August 25, 2023 at 8:36 AM, it was determined that the laboratory failed to attestated that the proficiency sample were tested in the same manner that they tested the laboratory patient samples. The findings include: 1.On August 25, 2023 at 8:30 AM the proficiency attestation staments since year 2022 were requested. The laboratory personnel did not provide any attestation stament since year 2022. 2. The testing personnel stated that she did not have or keep any attestation stament since year 2022. She also stated that she was hired on April 2023 and she never met the laboratory director, and not have instructions related to attestation staments documments.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on laboratory proficiency sample print outs, proficiency sample evaluation results, proficiency samples shipment schedule (provided by the Puerto Rico proficiency program), hematology quality control records and instrument data log; it was determined that the laboratory carried out inter-laboratory communications during the first and second hematology testing events of year 2022. The findings include: 1. The laboratory used Cell Dyn 3200 by Abbott to performed complete blood cunts (CBC). 2. Review of the Puerto Rico Proficiency testing (PRPTP) program shipment schedule dates, provided by the PRPTP on August 29, 2023 at 3:04 PM, showed that for the first testing event of year 2022 the samples were shipped on April 11, 2022. For the second testing event were shipped on June 6, 2022. 3. Reviewed the PRPTP shcedule showed that the report due date for the first testing event was May 6, 2022. For the second testing event was June 24, 2022. 4.Review of the instrument print outs provided during the survey by the testing personnel on August 25, 2022 at 8:45 AM showed the instrument print outs heading included Laboratorio Clinico Borges at Rio Piedras Puerto Rico as the testing site. 5. The print outs showed the following information for the first testing event year 2022: Event 2022-131 (1st Testing Event 2022) Analyte Event Result Print-out Neu% 77.7 77.7 Lym% 14.8 14.8 Mono% 3.6 3.59 Eos% 3.5 3.54 Baso% 0.3 0.276 RBC 5.12 5.12 HCT 44.2 44.2 HGB 16.4 16.4 WBC 20.6 20.6 PLT 557 557 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan). (Print out= Proficiency samples print outs from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite;

Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-132 (1st Testing Event 2022) Analyte Event Result Print-out Neu% 67.7 67.7 Lym% 21.8 21.8 Mono% 5.2 5.2 Eos% 4.3 4.25 Baso% 1.1 1.05 RBC 4.39 4.39 HCT 6.7 6.7 HGB 13.4 13.4 WBC 8.1 8.1 PLT 297 297 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan). (Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-133 (1st Testing Event 2022) Analyte Event Result Print-out Neu% 78.6 78.6 Lym% 12.4 12.4 Mono% 4.5 4.5 Eos% 3.6 3.6 Baso% 0.9 0.88 RBC 5.05 5.05 HCT 43.7 43.7 HGB 16.4 16.4 WBC 19.9 19.9 PLT 557 557 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan). (Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-134 (1st Testing Event 2022) Analyte Event Result Print-out Neu% 53.9 53.9 Lym% 38.6 38.6 Mono% 3.5 3.53 Eos% 3.6 3.60 Baso% 0.3 0.29 RBC 1.99 1.99 HCT 15.4 15.4 HGB 5.9 5.9 WBC 2.9 2.90 PLT 97 97 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan).(Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-135 (1st Testing Event 2022) Analyte Event Result Print-out Neu% 69.3 69.3 Lym% 19.8 19.8 Mono% 5.6 5.64 Eos% 4.1 4.07 Baso% 1.2 1.2 RBC 4.33 4.33 HCT 36.3 36.3 HGB 13.5 13.5 WBC 7.7 7.7 PLT 308 308 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan). (Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) 6. The print outs showed the following information for the second testing event year 2022: Event 2022-521 (2 nd Testing Event 2022) Analyte Event Result Print-out Neu% 51.7 51.7 Lym% 37.7 37.7 Mono% 6.7 6.7 Eos% 2.6 2.63 Baso% 1.4 1.35 RBC 2.08 2.08 HCT 15.3 15.3 HGB 5.92 5.92 WBC 3.1 3.08 PLT 125 125 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan). (Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-522 (2 nd Testing Event 2022) Analyte Event Result Print-out Neu% 69.0 69.0 Lym% 20.9 20.9 Mono% 4.9 4.9 Eos% 3.7 3.74 Baso% 1.5 1.5 RBC 4.51 4.51 HCT 37.9 37.9 HGB 13.8 13.8 WBC 8.0 8.01 PLT 316 316 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan).(Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-523 (2 nd Testing Event 2022) Analyte Event Result Print-out Neu% 74.7 74.7 Lym% 17.4 17.4 Mono% 3.3 3.30 Eos% 4.8 4.77 Baso% 0.3 0.345 RBC 6.12 6.12 HCT 52.5 52.5

	HGB 19.0 19.0 WBC 10.0 10.0 PLT 172 172 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan).(Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-524 (2 nd Testing Event 2022) Analyte Event Result Print-out Neu% 79.4 79.4 Lym% 11.6 11.6 Mono% 3.9 3.92 Eos% 4.9 4.9 Baso% 0.1 0.138 RBC 4.95 4.95 HCT 43.9 43.9 HGB 16.7 16.7 WBC 20.1 20.1 PLT 564 564 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan).(Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) Event 2022-525 (2 nd Testing Event 2022) Analyte Event Result Print-out Neu% 52.4 52.4 Lym% 31.9 31.9 Mono% 10.7 10.7 Eos% 2.5 2.50 Baso% 2.4 2.43 RBC 2.13 2.13 HCT 15.5 15.5 HGB 5.8 5.8 WBC 3.2 3.2 PLT 107 107 Legends: (Event Result= Event result reported to the Puerto Rico Proficiency Program by Laboratorio Clinico Risan). (Print out= proficiency samples print out from Laboratorio Clinico Borges find at Laboratorio Clinico Risan). (NEU= Neutrophil; Lym=Lymphocite; Mono=Monocyte; Eos=Eosinophil; Baso=Basophil; RBC=Red Blood Count; HCT= hematocrit; HGB=hemoglobin; WBC=White Blood Count; PLT=Platelet) 7. The test result reported by Laboratorio Clinico Risan (40D0658298) and the test results included in the Laboratorio Clinico Borges (40D0715748) print outs were same. 8. On August 25, 2023 at 10:05 AM the testing personnel stated that she was not the testing personnel during year 2022. She was hired on April 2023. She Also stated she doesn't know who is the laboratory director. 9. The hematology Quality control records and the instrument data log reviewed on August, 25, 2023 at 11:25 AM showed that the laboratory did not process patient samples or proficiency samples from April 7, 2022 to September 16, 2022. However they did report the proficiency samples processed at Laboratorio Clinico Borges as it owns.
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 syphillis serology quality control records review and interview with the laboratory testing personnel on August 25, 2023 at 12:50 PM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphillis serology tests. Refer to D 5405.
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 Quality Assessment (QA) activities records review and laboratory testing personnel interview on August 25, 2023 at 10:44AM, it was determined that laboratory failed to evaluate and monitor the general laboratory system requirements since March 2022. The findings include: 1. On August 25, 2023 at 10:20 AM, the laboratory QA was requested. The QA calendar showed that the laboratory must evaluate the general laboratory system every six months (february and August). 2. On August 25, 2023 at 10:20 AM the QA showed that the laboratory failed to evaluate and monitor the specimen identification and integrity, patient confidentiality, complaint investigation, communication, personnel competency and proficiency testin performance in the General Laboratory system since March 2022. 3. The laboratory testing personnel confirmed on August 25, 2023 at 10:44 AM that the laboratory failed to evaluate and monitor the general laboratory system requirements since March 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 Quality Assessment (QA) activities records review and laboratory testing personnel interview on August 25, 2023 at 10:44AM, it was determined that laboratory failed to evaluate and monitor the pre-analytic system requirements since January 2022. The findings include: 1. On August 25, 2023 at 10:20 AM, the laboratory QA was requested. The QA calendar showed that the laboratory has established that the laboratory must evaluated the pre-analytic system annually (August). 2. On August 25, 2023 at 10:20 AM the QA showed that the laboratory failed to evaluate and monitor the test request, specimen submission and handling, specimen referral in the pre-analytic system since January 2022. 3. The laboratory testing personnel confirmed on August 25, 2023 at 10:44 AM that the laboratory failed to evaluate and monitor the pre-analytic system requirements since January 2022.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Syphilis Serology (Rapid Plasma Reagin (RPR)) quality control records review (years 2022 to 2023) and interview with the laboratory testing personnel on August 25, 2023 at 12:30PM, it was determined that the laboratory did not include, each day of patient testing, the reactive, weakly reactive nor the non reactive control

	materials when 265 patients specimens were tested and reported for RPR from January 2022 to August 2023. The findings include: 1. The laboratory use ASI RPR Card testing method to perform the Syphilis qualitative test. The manufacturer instructed the laboratory to include the three (3) control levels. 2. On August 25, 2023 at 12:30 PM, the syphilis serology quality control record was reviewed and showed that the laboratory did not include each day of patient testing the reactive, weakly reactive nor the non reactive control materials from January 2022 to August 2023. 3. The laboratory testing personnel confirmed on August 25, 2023 at 12:50 PM, that the laboratory failed to include each day of patient testing the reactive, weakly reactive and non reactive control material when 265 patient samples were processed and reported from January 2022 to August 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on laboratory daily checks sheet review, laboratory quality control records review and laboratory testing personnel interview on August 25, 2023 at 12:13 PM, it was determined that the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, voltage, refrigerator and freezer temperatures and the preventive maintenance of the eye wash station since March 26, 2022. The findings include: 1. The laboratory daily checks sheet was reviewed on August 25, 2023 at 12:00 PM; the manual showed that the laboratory must monitor and document daily the room temperature, relative humidity, voltage, refrigerator and freezer temperatures and the preventive maintenance of the eye wash station. 2. Since March 26 2022 the laboratory did not monitor and document the daily the room temperature, relative humidity, voltage, refrigerator and freezer temperatures and the preventive maintenance of the eye wash station. (Reviewed on August 25, 2023 at 12:00 PM) 4. The laboratory testing personnel confirmed on August 25, 2023 at 12:13 PM, that the laboratory did not monitor and document the room temperature, relative humidity, voltage, refrigerator and freezer temperatures and the preventive maintenance of the eye wash station.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on Human Chorionic gonadotropin (hCG) control records reviewed and interview with laboratory testing personnel on August 25, 2023 at 12:24PM; it was determined that the laboratory failed to perform the performance specifications of the new hCG reagent kit. The laboratory begin to use a new manufacturer on April 18, 2023. The laboratory processed and reported 4 patient's sample between April 18, 2023 to May 25, 2023. The findings include: 1. On August 25, 2023 at 12:20 PM the quality control records were reviewed, (year 2022 and 2023), and showed that the laboratory change their Human Chorionic gonadotropin (hCG) manufacturer. The new manufacturer was Alere hCG 2.The laboratory did not verify the manufacturer specifications prior to put in use on April 18, 2023. 3. On August 25, 2023 at 12:24 PM, the testing personnel confirmed that the laboratory fail to performed and document the verify of performance specification when change the manufacturer for the Alere hCG. The laboratory processed and reported 4 patient's sample from April 18, 2023 to May 25, 2023..
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 laboratory peripheral instruments daily checks sheet review and laboratory testing personnel interview on August 25, 2023 at 12:13 PM, it was determined that the laboratory failed to perform and document the following peripheral equipment daily ckecks: centrifuge maintenance and microscope maintenance since March 26, 2022. The findings include: 1. The laboratory peripheral instrument daily checks sheet was reviewed on August 25, 2023 at 12:00 PM and the laboratory centrifuge maintenance log sheet showed that every day the laboratory must perform the following: wipe exterior and interior. 2. The laboratory peripheral instrument daily checks sheet was reviewed on August 25, 2023 at 12:00 PM and the laboratory microscope maintenance log sheet showed that every day the laboratory must perform the following: clean occular and objective. 3. The record showed that the laboratory did not perform nor document daily maintenance since March 26, 2022. . 4. The laboratory testing personnel confirmed on August 25, 2023 at 12:13 PM, that the laboratory did not monitor and document the centrifuge maintenance and microscope maintenance.
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 the Urinalysis quality control records review and interview with the laboratory testing personnel on August 25, 2023 at 11:13 AM; it was determined that the laboratory did not include negative microscopic sediment control material when 1,394 patient's were process and reported since January 2022. The findings include: 1. The Urinalysis quality control records were reviewed on August 25, 2023 at 10:53 AM, and showed that the laboratory did not include a negative microscopic control for urinalysis sediment. 2. The laboratory testing personnel confirmed on August 25, 2023 at 11:13 AM that the laboratory did not implemented the use of a negative control material for urine sediment. She state that 1,394 were processed and reported for urine sediment.
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 Quality Assessment (QA) activities records review and laboratory testing personnel interview on August 25, 2023 at 10:44AM, it was determined that laboratory failed to evaluate and monitor the test procedures, the analytic system requirements since January 2022. The findings include: 1. On August 25, 2023 at 10: 20 AM, the laboratory QA was requested. The QA calendar showed that the laboratory has established that the laboratory must evaluated the analytic system requirements annually (December). 2. On August 25, 2023 at 10:20 AM the QA showed that 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 since January 2022. 3. The laboratory testing personnel confirmed on August 25, 2023 at 10:44 AM that the laboratory failed to evaluate and monitor the analytic system requirements since January 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 Quality Assessment records review (QA) and laboratory testing personnel interview on August 25, 2023 at 10:44 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the post-analytic systems requirements since January 2022. The findings include: 1. On August 25, 2023 at 10:20 AM, the laboratory QA was requested. The QA calendar showed that the laboratory has established that the laboratory must evaluated the post-analytic system annually. 2. On August 25, 2023 at 10:20 AM the QA showed that the laboratory did not evaluate practices related to: result evaluation, result sent to interfaced since January 2022. 3. The laboratory testing personnel confirmed on August 25, 2023 at 10:44 AM that the laboratory failed to evaluate and monitor the post-analytic system requirements since January 2022.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Syphilis Serology (Rapid Plasma Reagin (RPR)) manufacturer's instructions, Human chorionic gonadotropin (hCG) perfomance specification, daily checks review and laboratory testing personnel interview on August 25, 2023 at 1:30 PM, it was determined that the testing personnel did not follow the quality control requirements.Refer to D5405, D5413, D5421, D5435, D5445.
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 quality control records and lack of quality assessment and laboratory testing personnel interview on August 25, 2023, at 1:25 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 D6093 and D6094.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (years 2022 and 2023) and laboratory testing personnel interview on August 25, 2023 at 8:36 AM, it

	was determined that the laboratory director did not asure that the proficiency samples were not referred to another laboratory. Refer D 2013.
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 quality control records (year 2022 to 2023) review and testing personnel interview on August 25, 2023 at 1:00PM, it was determined that the laboratory director failed to ensure that the quality control procedures, maintenance and verification of performance that were established and followed. Refer to D5405, D5413, D5421, D5435, D5445.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Quality Assesstment (QA) records reviewed and interview with the laboratory testing personnel on August 25, 2023 at 10:44 AM; it was determined that the laboratory director failed to ensure the compliance with QA requirements during years 2022 and 2023. Refer to D5291, D5391, D5791 and D5891.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on quality control records review, evaluation of testing personnel competence and interview with the laboratory testing personnel on August 25, 2023 at 1:30 PM, it was determined that the laboratory technical supervisor failed to fulfill his responsibilities and duties. Refer to D6115, D6117 and D6120.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on review of pregnancy quality control records and interview with the laboratory testing personnel on August 25, 2023 at 12:24 PM, it was determined that the technical supervisor did not perform the evaluation of the performance specification of the new hCG reagent kit prior to begin patient testing (year 2022 and 2023). Refer to D5421.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: 1. Based on urinalysis quality control records review from January 2022 to August, 2023, and laboratory testing personnel interview on August 25, 2023 at 11:13 AM, it was determined that the laboratory technical supervisor failed to fulfill her responsibility to ensure that the laboratory follow the urinalysis quality control that was established. Refer to D5445. 2. Based on syphilis serology control records review from January 2022 to August, 2023, and laboratory testing personnel interview on August 25, 2023 at 12:50 PM, it was determined that the laboratory technical supervisor did not ensure that the testing personnel (MT #7376) follow the established RPR quality control program. Refer to D5449.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel records and interview with the laboratory testing personnel on August 25, 2023 at 8:15 AM, it was determined that the technical supervisor did not perform the training of the new testing personnel (MT #7376) hired on April 2023. The finding includes: 1. The testing personnel (MT #7376) was hired and began to perform patient testing on April 2023. No training was given nor document.