

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0872956	(X3) Date Survey Completed 05/07/2025
Name of Provider or Supplier Laboratorio Clinico Garnier	Street Address, City, State Barrio Guaraguao Abajo Carr 174, Km 5, Hm 7, Bayamon, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey on May 7, 2025. Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1100 Condition: Facility Administration 42 C.F.R. 493.1210 Condition: Routine Chemistry 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; Laboratory director. In addition, the laboratory was found out of compliance with the following conditions: 42 C.F.R. 493.1208 Condition: General Immunology 42 C.F.R. 493.1212 Condition: Endocrinology
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the routine chemistry proficiency report sheet (Puerto Rico Proficiency Program second event 2024) and interview with the laboratory director on May 6, 2025, at 11:45 AM; it was determined that the proficiency samples (2024 - 391, 2024 -392, 2024 -393, 2024 - 394, 2024 - 395) corresponding to the second chemistry event of 2024, the laboratory conducted duplicate analyses for all analytes in which it's participating. The findings include: 1. On May 6, 2025, at 11:45 AM, the routine chemistry proficiency testing records were reviewed. 2. On May 6, 2025 at 11:46 AM, review of the routine chemistry proficiency report sheet (Puerto Rico Proficiency Program second event year 2024) showed that the Alanine transaminase (ALT), Albumin, Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), Bilirubin total, Calcium, Chloride, Cholesterol total, High - density lipoprotein (HDL), Creatinine, Glucose, Potassium, Sodium, Total Protein, Triglycerides (TG) and Blood Urea Nitrogen (Bun), were documented in duplicate. 3. On May 6, 2025, at 12:30 PM, the laboratory director was interviewed, she stated that the patient's sample</p>

	<p>were not tested in duplicate. She confirmed that the proficiency sample for the second testing event of year 2024 were processed more than once.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>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).</p> <p>This CONDITION is not met as evidenced by: Based on lack of routine chemistry proficiency testing records (printouts years 2024 - 2025), routine chemistry quality control record (years 2024-2025), Quality Assessment records (QA) (year 2024-2025) and laboratory director interview on May 7, 2025 at 1:30 PM, it was determined that the laboratory failed to keep printouts proficiency report sheet, quality control records, calibration verification record, preventive maintenance service log and QA records for routine chemistry at least two (2) years. Refer to: D3031 and D3037.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality control records, calibration verification record, preventive maintenance service log and QA records for routine chemistry analyte (ALT, Albumin, ALP, AST, Bilirubin total, Calcium, Chloride, Cholesterol total, HDL, Creatinine, Glucose, Potassium, Sodium, Total Protein, TG and Bun) (years 2024 and 2025), and laboratory director interview May 7, 2025 at 1:30 PM, it was determined that the laboratory failed to retain the quality control of this test for at least two (2) years; when processed and reported 107,703 out of 107,703 analytes for routine chemistry patient samples from January 1, 2024, to May 5, 2025. The findings include: 1. On May 7, 2025, at 9:00 AM, routine chemistry quality control was requested. A tour was carried out and no evidence of documentation regarding the quality control of the tests was found. 2. On May 7, 2025, at 9:36 AM, the laboratory director stated that the records of quality control for the years 2024 and 2025 of the routine chemistry were not available at the time of inspection. 3. On May 7, 2025, at 10:52 AM, the laboratory director confirmed that quality control for the years 2024 and 2025 was not available. The laboratory director stated that RX Daytona quality control is not linked to the Laboratory Information System (LIS), only the transmission of patient reports. 4. The laboratory processed and reported 107,703 out of 107,703 analytes for routine chemistry patient samples from January 1, 2024, to May 5, 2025.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p>

(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of Puerto Rico Proficiency Testing records (PRPT) (years 2024-2025) and laboratory director interview on May 6, 2025, at 11:35 AM, it was determined that the laboratory failed to retain routine chemistry proficiency testing records for at least 2 years, when processed and reported 107,703 analytes for routine chemistry. The findings include: 1. The Puerto Rico Proficiency Testing records were reviewed from February 2024 to February 2025. (Reviewed on May 6, 2025, at 11:35 AM). 2. The laboratory did not have available documentation (results printouts reported) from the following testing events: first testing event of 2024, second testing event of 2024, third testing event of 2024 and first testing event of 2025 for routine chemistry test performed by RX Daytona Clinical Chemistry Analyzer. (Reviewed on May 6, 2025, at 12:20 PM). 3. On May 6, 2025, at 12:30 PM, the laboratory director was interviewed, she states that the RX Daytona chemistry analyzer has transmission problems. She confirmed that the laboratory did not have available the Proficiency Testing printout results from those testing events performed in 2024 and 2025.

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 Mycoplasma pneumoniae quality control records patient records review (years 2024-2025) and interview with the laboratory director on May 6, 2025, at 4:00 PM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. Refer to: D5449 (A), D5413 an D5471(A) The finding includes: 1. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to D5449 (A) 2. The laboratory failed to follow the manufacturer's instruction regarding to the temperature (22 C to 25 C). Refer to D5413. 3. The laboratory did not evaluate the new lot of Mycoplasma pneumoniae test for positive and negative reactivity prior to placing it in routine use. Refer to D5471 (A)

D5016

ROUTINE CHEMISTRY

CFR(s): 493.1210

If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on routine chemistry quality control records review (years 2024-2025) and

	<p>interview with the laboratory director on May 7, 2025, at 1:30 PM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry test. Refer to D5401, D5429, D5439, D5447 and D5469.</p>
D5020	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on Human Chorionic Gonadotropin (hCG) quality control records review (years 2024 - 2025) and interview with the laboratory director on May 6, 2025, at 3:55 PM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for Endocrinology test. Refer D5449 (B) and D 5471 (B). The findings include: 1. The laboratory did not include an external positive and negative control material each day of patient testing. Refer to D5449 (B). 2. The laboratory did not evaluate the new lot of hcG test for positive and negative reactivity prior to placing it in routine use. Refer to D5471 (B).</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A. Based on the review of written personnel competence policies, personnel records, and interview with the laboratory director on May 6, 2025, at 9:30 AM, it was determined that the laboratory director failed to follow the established schedule for personnel competence evaluations. The findings include: 1. The written policy for personnel competence stated that the laboratory must perform competence procedures annually. (Reviewed on May 6, 2025, 2025, at 9:30 A.M.) 2. The personal records review, on May 6, 2025, at 9:32 AM, showed that the last competence evaluation of technical supervisor and testing personnel was performed on August 15, 2023. 3. The laboratory director confirmed on May 6, 2025, at 10:25 AM, that the competence evaluation for the technical supervisor and testing personnel was not performed as established (annually) in year 2024. B. Based on personnel records review (year 2025) and laboratory director interview on May 6, 2025, at 9:40 AM, it was determined that the laboratory failed to follow the established schedule for competence evaluation for the clinical consultant. The finding includes: 1. The laboratory written policy for personnel competence procedures showed that competence procedures perform annually. (Reviewed on May 6, 2025, at 9:40 AM) 2. The personal records review, on May 6, 2025, at 9:42 AM, showed that the last competence evaluation for the clinical consultant a was performed on March 1, 2024. 3. The laboratory director confirmed on May 6, 2025, at 10:25 AM, that the competence evaluation for the clinical consultant was not performed as established (annually) in year 2025.</p>
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) program review (years 2024-2025) and laboratory director interview on May 6, 2025, at 10:15 AM, it was determined that the laboratory failed to follow the established QA program to monitor and evaluate the following requirements for General laboratory systems: patient confidentiality, specimen identification and integrity, complaint investigations, communications and personnel competency. The findings include: 1. On May 6, 2025, at 10:15 AM, review of the laboratory QA program showed that the laboratory must evaluate, annually, the following: patient confidentiality, specimen identification and integrity, complaint investigations, communications and personnel competency. 2. The records showed that the laboratory performed the last evaluation during the year 2023. No evaluation for the years 2024 and 2025 were performed. 3. The laboratory director confirmed during the interview on May 6, 2025, at 11:30 AM, that the general systems QA evaluations were not performed since year 2024.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) program review (years 2024-2025) and laboratory director interview on May 6, 2025, at 10:35 AM, it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for preanalytical systems: patient test requests and specimen submission, handling and referral. The findings include: 1. On May 6, 2025, at 10:35 AM, a review of the laboratory QA program showed that the laboratory must evaluate, annually, the following: patient test requests and specimen submission, handling and referral. 2. The records showed that the laboratory performed the last evaluation during the year 2023. No evaluation for the years 2024 and 2025 were performed. 3. The laboratory director confirmed during the interview on May 6, 2025, at 11:30 AM, that the preanalytical systems QA evaluations were not performed since for the year 2024.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on lack of routine chemistry quality control (years 2024 -2025) and laboratory director interview on May 6, 2025, at 9:45 AM, it was determined that the laboratory failed to have the procedure manual for routine chemistry. The findings include: 1. The laboratory performed routine chemistry by RX Daytona Chemistry Analyzer. (Reviewed on May 6, 2025, at 9:45 AM). 2. The laboratory did not have a routine chemistry procedure manual. 3. The laboratory director stated on May 6, 2025, at 11: 30 AM, that the procedure manual for routine chemistry was not found in the laboratory.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review (years 2024-2025) and interview with the laboratory director on May 6, 2025, at 2:15 PM, it was determined that the laboratory failed to follow the manufacturer's instruction when 192 out of 192 patient's specimens were tested and reported by Mycoplasma pneumoniae from January 2, 2024, to May 1, 2025. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test to perform the Mycoplasma pneumoniae qualitative tests. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 C to 25 C. (Reviewed on May 6, 2025, at 2:17 PM) 3. On May 6, 2025, at 2:17 PM, 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 by Mycoplasma by Immuno Card Meridian method from January 2, 2024, to May 1, 2025. 4. The laboratory director confirmed on May 6, 2025, at 2:20 PM, that the laboratory did not monitor nor document the room temperature when it processed the patient's specimens for Mycoplasma pneumoniae test.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
A. Based on manufacturer's specifications, lack routine chemistry preventive maintenance records review (years 2024 - 2025) and laboratory director interview on May 7, 2025, at 9:50 AM., it was determined that the laboratory failed to perform and

document the preventive maintenance as required by manufacturer of the RX Daytona Chemistry Analyzer, when processed and reported 107,703 out of 107,703 routine chemistry analytes from January 1, 2024, to May 5, 2025. The findings include: 1. The laboratory uses RX Daytona Chemistry Analyzer to perform routine chemistry patient tests. 2. The manufacturer's specifications establishes: "twice yearly preventive maintenance service". 3. Review of lack preventive maintenance records from January 2024 to May 5, 2025, showed that the laboratory did not perform nor document the twice-yearly preventive maintenance service. 4. The laboratory processed and reported 107,703 out of 107,703 routine chemistry analytes from January 1, 2024, to May 5, 2025. 5. The laboratory director confirmed on May 7, 2025, at 10:00 AM, that the laboratory failed to follow the manufacturer's specifications for the preventive maintenance of RX Daytona Chemistry Analyzer. B. Based on manufacturer's specifications, lack routine chemistry daily maintenance record review (year 2025) and laboratory director interview on May 7, 2025, at 9:50 AM., it was determined that the laboratory failed to perform the daily maintenance as required by manufacturer of the RX Daytona Chemistry Analyzer, when processed and reported 30,957 out of 30,957 routine chemistry analytes from January 1, 2025, to May 5, 2025. The findings include: 1. The laboratory uses RX Daytona Chemistry Analyzer to perform routine chemistry patient tests. 2. The manufacturer's specifications establishes that the laboratory must document and perform the daily preventive maintenance: a. Daily preventive maintenance: check the remaining volumes of wash solutions in tank and refill if necessary, check supply tube end is at bottom of system water tank, empty waste tanks, ensure there is sufficient printer paper, use an absorbent cloth to remove any condensation in the RCU tray, clean the outside of sample and reagent probes with alcohol, check the remaining volume of calibrator A and ensure tip of Calibrator A tube is at the bottom of the bottle, check the reagent volumes. 3. Review of lack daily maintenance records review from January 2025 to May 5, 2025, showed that the laboratory did not perform nor document the daily preventive maintenance. 4. The laboratory processed and reported 30,957 out of 30,957 routine chemistry analytes from January 1, 2025, to May 5, 2025. 5. The laboratory director confirmed on May 7, 2025, at 10:15 AM, that the laboratory failed to follow manufacturer's specifications for the daily preventive maintenance of RX Daytona Chemistry Analyzer.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

(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 lack routine chemistry calibration verification records review (years 2024 - 2025) and laboratory director interview on May 7, 2025, at 9:15 AM , it was found that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests processed by the RX Daytona Chemistry Analyzer ,when processed and reported 107,703 out of 107,703 routine chemistry analytes from January 1, 2024, to May 5, 2025. The findings include: 1. The laboratory used the RX Daytona Chemistry Analyzer to perform routine chemistry tests. 2. The laboratory did not perform the calibration verification procedure since December 27, 2023. 3. The laboratory director stated on May 7, 2025, at 9:20 AM, that the calibration verification had not carried us during the year 2024 and 2025. 4. The laboratory processed and reported 107,703 out of 107,703 routine chemistry analytes from January 1, 2024, to May 5, 2025.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
Based on the lack of routine chemistry quality control records review (years 2024- 2025) and laboratory director interview on May 7, 2025, at 9:00 AM, it was determined that the laboratory failed to include two level of control materials of different concentrations prior to perform patient, each day of routine chemistry patients, when processed and reported 107,703 out of 107,703 analytes for routine chemistry patient samples from January 1, 2024, to May 5, 2025. The findings include: 1. The laboratory uses RX Daytona Chemistry Analyzer to perform routine chemistry patient tests. 2. On May 7, 2025, at 9:00 AM, the routine chemistry quality control records were requested. 3. The laboratory director stated on May 7, 2025, at 9: 05 AM, that the laboratory used two levels of control material (I and II) must be included each day of patient testing. The laboratory director confirmed that the quality control records (years 2024 - 2025) were not available at the time of inspection. 4. The laboratory director confirmed on May 7, 2025, at 9:15 AM, that the laboratory did not have any quality control records of routine chemistry tests for the year 2024 -2025. The laboratory director confirmed that the laboratory processed and reported 107,703 out of 107,703 analytes for routine chemistry patient samples from January 1, 2024, to May 5, 2025.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:
A. Based on Mycoplasma pneumoniae quality control records review (years 2024 - 2025) and laboratory director interview on May 6, 2025, at 2:15 PM, it was determined that the laboratory did not include external positive and negative control material each day of Mycoplasma pneumoniae patient testing when reported and performed 192 out of 192 Mycoplasma patient's samples from January 2, 2024, to

May 1, 2025. The findings include: 1. The laboratory performed Mycoplasma Pneumoniae test by ImmunoCard method. 2. Review of the Mycoplasma pneumoniae quality control records on May 6, 2025, at 2:15 PM, showed that the laboratory did not include the external positive and negative control material each day of patient testing. 3. The laboratory processed and reported 192 patient's sample from January 2, 2024, to May 1, 2025. 4. The laboratory director confirmed on May 6, 2025, at 2:25 PM, that the laboratory did not include a positive and negative external control material each day of patient testing. B. Based on the Human Chorionic Gonadotropin (hCG) quality control records (years 2024 - 2025) and laboratory director interview on May 6, 2025, at 2:00 PM, it was determined that the laboratory did not include external positive and negative control material each day of hCG patient testing when reported and performed 56 out of 56 hCG patient's samples from January 31, 2024, to April 8, 2025. The findings include: 1. The laboratory performed hCG test by FaStep method. 2. Review of the hCG quality control records on May 6, 2025, at 2:00 PM, showed that the laboratory did not include the external positive and negative control material each day of patient testing. 3. The laboratory processed and reported 56 patient's sample from January 31, 2024, to April 8, 2025. 4. The laboratory director confirmed on May 6, 2025, at 2:15 PM, that the laboratory failed to include the positive and negative external control material each day of patient testing.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:
A. Based on observation, lack of routine chemistry quality control documentation and laboratory director interview on May 6, 2025, at 3:10 PM, it was determined that the laboratory failed to verify manufacture's stated value of the control material (Lot. 331001 and 331002), prior to placing in routine use on May 2, 2025. The findings include: 1. The laboratory performed routine chemistry by RX Daytona Chemistry Analyzer. (Reviewed on May 6, 2025, at 3:10 PM) 2. On May 6, 2025, at 3:30 PM, it was observed that the laboratory had in use the following routine chemistry control lot: (Reviewed on May 6, 2025, at 3:30 PM) - Pointe Chemical Controls Level I Control Lot. 331001, Exp. 2027-08-31 - Pointe Chemical Controls Level II Control Lot. 331002, Exp. 2027-10-31 3. The verification of the manufacturers stated values were requested to the laboratory director. She confirmed on May 6, 2025, at 4:00 PM, that no evaluations of the stated lots of control materials were performed prior to placing them in routine use. B. Based on lack of routine chemistry Levey-Jennings control chart from years 2024-2025, laboratory information system (LIS) data, and interview with the laboratory director on May 7, 2025, at 9:20 AM., it was found that the laboratory did not evaluate nor define the statistical values of the commercial control materials used by the RX Daytona Chemistry Analyzer when processed and reported 107,703 out of 107,703 routine chemistry analytes from January 1, 2024, to

May 5, 2025. The findings include: 1. The laboratory did not have any statistical data (Levey-Jennings control chart , control value means and limits) of the control materials used from January 1, 2024, to May 5, 2025. 2. The laboratory director stated on May 7, 2025, at 9:30 AM. that for the years 2024 and 2025 the laboratory did not have the evaluations of the control results to detect any outliers, shifts or trends in control values. 3. The laboratory information system data showed that the laboratory processed and reported 107,703 out of 107,703 routine chemistry analytes from January 1, 2024, to May 5, 2025.

D5471

CONTROL PROCEDURES
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

This STANDARD is not met as evidenced by:
A. Based on Mycoplasma pneumoniae quality control records review (year 2024 -2025) and laboratory director interview on May 6, 2025, at 2:30 P.M, it was determined that the laboratory did not evaluate the new lots of Mycoplasma pneumoniae test for positive and negative reactivity prior to placing it in routine use from September 19, 2024 through January 3, 2025. The findings include: 1. The laboratory performed a Mycoplasma Pneumoniae test by Immuno Card method. 2. The Mycoplasma Pneumoniae quality control records were reviewed from January 2, 2024, to May 1, 2025, and showed that the laboratory did not evaluate the new lot of Mycoplasma pneumoniae test for positive and negative reactivity prior to placing it in routine use: - Lot Number: 7865.1126, Expiration date :11/21/25, Date opened: 9/19 /24, Patient processed and reported: 32 patients - Lot Number: 7865.1131, Expiration date :1/29/26, Date opened: 1/3/25, Patient processed and reported: 26 patients 3. The laboratory performed and reported 58 out of 58 Mycoplasma Pneumoniae patient samples from September 19, 2024, to May 1, 2025. (Reviewed on May 6, 2025, at 2: 32 PM) 4. The laboratory director confirmed on May 6, 2025, at 2:35 P.M., that the laboratory did not evaluate the new lot of Mycoplasma Pneumoniae test for positive and negative reactivity prior to placing it in routine use. B. Based on human chorionic gonadotropin (hCG) test quality control records review (year 2024 -2025) and laboratory director interview on May 6, 2025, at 2:15 P.M, it was determined that the laboratory did not evaluate the new lots of hCG test for positive and negative reactivity prior to placing it in routine use, on January 20, 2025. The findings include: 1. The laboratory performed hCG test by FaStep method. 2. The hCG quality control test records were reviewed from January 2, 2024, to April 8, 2025, and showed that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use: Lot Number: 31572, Expiration date :11/30 /25, Date opened: 1/20/25. 3. The laboratory performed and reported 12 out of 12 hCG patient samples. (Reviewed on May 6, 2025, at 2:20 P.M.) 4. The laboratory director confirmed on May 6, 2025, at 2:15 P.M., that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

(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 urinalysis testing records review and interview with the laboratory director on May 7, 2025, at 1:10 PM, it was determined that three urinalysis final test results did not include the identify of the testing personnel who performed the test. The findings include: 1. During the recertification survey on May 7, 2025, it was observed that the laboratory director processed three urinalysis patient's samples. 2. Review of the three urinalysis test records identified as testing personnel the technical supervisor, not the laboratory director. 3. This infomation was confirmed with the laboratory director, during interview on May 7, 2025, at 1:25 PM.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) program review (years 2024-2025) and laboratory director interview on May 6, 2025, at 10:45 AM, it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for analytic system since year 2024: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, equipment/instrument/test/system maintenance and function checks, calibration and calibration verification, control procedures, comparison of test results, corrective actions and patient test records. The findings include: 1. On May 6, 2025, at 10:45 AM, a review of the laboratory QA program showed that the laboratory must evaluate, annually, the following: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, equipment /instrument/test/system maintenance and function checks, calibration and calibration verification, control procedures, comparison of test results, corrective actions and patient test records. 2. The records showed that the laboratory performed the last evaluation during the year 2023. No evaluation for the years 2024 and 2025 were performed. 3. The laboratory director confirmed during the interview on May 6, 2025, at 11:30 AM, that the analytic systems QA evaluations were not performed since for the year 2024.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems

identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) program review (years 2024-2025) and laboratory director interview on May 6, 2025, at 11:20 AM, it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for postanalytical systems: patient test reports and turn around time (TAT). The findings include: 1. On May 6, 2025, at 11:20 AM, a review of the laboratory QA program showed that the laboratory must evaluate, annually, the following: patient test reports and turn around time (TAT). 2. The records showed that the laboratory performed the last evaluation during the year 2023. No evaluation for the years 2024 and 2025 were performed. 3. The laboratory director confirmed during the interview on May 6, 2025, at 11:30 AM, that the postanalytic systems QA evaluations were not performed since for the year 2024.

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 (QA) (years 2024-2025) and laboratory director interview on May 7, 2025, at 2:30 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 D6093.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) 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 record review (routine chemistry second testing event year 2024) and laboratory director interview on May 6, 2025, at 12:30 PM; it was determined that the laboratory director failed to ensure that the proficiency samples were tested the same number of times as the patient samples. Refer to D2010.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on lack of quality control records and lack of quality assessment (QA) (years 2024-2025) and interview with the laboratory director on May 7, 2025, at 2:30 PM; it was determined that the laboratory director failed to ensure compliance with the analytic requirements (endocrinology, general immunology and routine chemistry) and the quality assessment program. Refer to D5291, D5391, D5401, D5413, D5429, D5439, D5447, D5449, D5469, D5471, D5791, and 5891.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

(b)(4) 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:
Based on lack of quality control records and lack of quality assessment (QA) (years 2024-2025) and interview with the laboratory director on May 7, 2025, at 2:30 PM; it was determined that the technical supervisor failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements for endocrinology, general immunology and routine chemistry specialties. Refer to D5291, D5391, D5401, D5413, D5429, D5439, D5447, D5449, D5469, D5471, D5791 and D5891.