

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0675423	(X3) Date Survey Completed 08/05/2026
Name of Provider or Supplier Laboratorio Clinico Rosario	Street Address, City, State Calle C Blq A-24 Jardines De Carolina, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced Clinical Laboratory Improvement Amendments (CLIA) recertification survey at Laboratorio Clinico Rosario on August 5, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on August 5, 2026, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1212 ENDOCRINOLOGY 42 CFR 493.1403 LABORATORY DIRECTOR
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on endocrinology quality control records review (years 2024 - 2026) and interview with the Technical Consultant (CT) on August 5, 2026, at 1:00 p.m., the laboratory failed to ensure compliance with the analytic system requirements for Endocrinology test. Refer to D5449 (A).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on review of Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024 - 2026), Hematology Proficiency Testing (PT) scores (year 2025), and interview with the Technical Consultant (CT) on August 5, 2026, at 10:34 a.m., the laboratory failed to evaluate the accuracy of patient testing for the Hematology specialty (Complete Blood Count (CBC) and White Blood Cell (WBC) 5-Parameter testing), when the PT provider assigned an artificial score of 100 percent. The laboratory processed and reported 2,358 out of 2,358 CBC patient tests from June 2025 through November 2025. The findings include: 1. CASPER and PRPTSP (Hematology PT) scores were reviewed from May 2024 through August 2026. 2. Review of the hematology PT scores for the third testing event in 2025 showed that the PT provider assigned an artificial score of 100 percent for CBC and WBC 5-Parameters testing. The results were not evaluated. 3. During interview on August 5, 2026, at 10:34 a.m., with the Technical Consultant (CT), the evaluation of the accuracy of the excused Hematology specialty (Complete Blood Count (CBC) and White Blood Cell (WBC) 5- Parameter) was required. The CT stated that the laboratory did not evaluate the accuracy of the CBC and WBC (5- Parameter). 4. The laboratory processed and reported 2,358 out of 2,358 CBC patient tests from June 2025 through November 2025. 5. The Technical Consultant (CT) confirmed on August 5, 2026, at 11:15 a.m., that the laboratory did not evaluate the accuracy of the Hematology specialty test.
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 review of the laboratory's written procedure manual, Mycoplasma patient testing worksheet and interview with the Technical Consultant (CT) on August 5, 2026, at 1:30 p.m., the laboratory failed to have a written procedure for Mycoplasma pneumoniae testing. The laboratory performed and reported 210 of 210 Mycoplasma pneumoniae patient specimens from August 4, 2025, through July 27, 2026. The findings include: 1. The laboratory performed qualitative Mycoplasma pneumoniae testing using the ImmunoCard Mycoplasma test system. 2. On August 5, 2026, at 1:30 p.m., the laboratory's written procedure for Mycoplasma pneumoniae testing was requested. The laboratory did not provide a written procedure for Mycoplasma pneumoniae testing. 3. Review of the Mycoplasma patient testing worksheet showed, that the laboratory performed and reported 210 of 210 Mycoplasma pneumoniae patient specimens from August 4, 2025, through July 27, 2026. 4. On August 5, 2026, at 1:55 p.m., the Technical Consultant (CT) confirmed during interview that the laboratory did not have a written procedure for Mycoplasma pneumoniae testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's endocrinology procedure manual, human Chorionic Gonadotropin (hCG) patient testing worksheet and interview with the Technical Consultant (CT) on August 5, 2026, at 1:05 p.m., the laboratory failed to include in their endocrinology procedure manual any instructions regarding the quality control (QC) procedure. The laboratory performed and reported 79 out of 79 hCG patient specimens from September 6, 2024, through August 1, 2026. The findings include: 1. On August 5, 2026, at 1:05 p.m., the laboratory's endocrinology (hCG) written procedure manual was requested. 2. On August 5, 2026, at 1:10 p.m., review of the laboratory's endocrinology written procedure manual showed that the manual did not include written quality control procedures for hCG testing. 3. Review of the hCG patient testing worksheet showed that the laboratory performed and reported 79 out of 79 hCG patient specimens from September 6, 2024, through August 1, 2026. 4. On August 5, 2026, at 1:24 p.m., the Technical Consultant (CT) confirmed during interview that the laboratory did not have a written quality control procedure for hCG testing in its procedure manual.

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 review of human chorionic gonadotropin (hCG) quality control records (years 2024-2026), hCG patient testing records, and interview with the Technical Consultant (CT) on August 5, 2026, at 1:00 p.m., the laboratory failed to include a negative and positive control materials each day of hCG patient testing, when the laboratory performed and reported 79 out of 79 hCG patient specimens from September 6, 2024, through August 1, 2026. The findings include: 1. Review of the hCG quality control record and patient testing records showed that the laboratory used the following hCG test kits:(Revised on August 5, 2026, at 1:00 p.m.) a. AimStep Combo Pregnancy (Lot 22016 / 2025-01-31) Used dates: September 6, 2024, through November 22, 2024. Patient specimens performed and reported: 5 b. Alere hCG (Lot 0000953985/ 2027-01-01) Used dates: January 14, 2026, through May 18, 2026. Patient specimens performed and reported: 63 c. AllTest Pregnancy Rapid Combo

(Lot ATHCG 26010020/ 2028-01-22) Used dates: June 9, 2026, through August 1, 2026. Patient specimens performed and reported: 11 2. The hCG quality control and patient testing records showed that the laboratory did not include a negative and a positive control material each testing day of hCG patient testing. 3. The laboratory performed and reported 79 out of 79 hCG patient specimens from September 6, 2024, through August 1, 2026. 4. During interview, the Technical Consultant (CT) confirmed on August 5, 2026, at 1:24 p.m., that the laboratory failed to include negative and positive control material each day hCG patient testing was performed. B. Based on review of Mycoplasma pneumoniae quality control records (year 2025 -2026), Mycoplasma patient testing record and interview with the Technical Consultant (CT), on August 5, 2026, at 1:30 p.m., the laboratory failed to include a negative control material at least once each day Mycoplasma pneumoniae patient testing was performed. The laboratory performed and reported 210 out of 210 Mycoplasma pneumoniae patient specimens from August 4, 2025, through July 27, 2026. The findings include: 1. The laboratory performed qualitative Mycoplasma pneumoniae testing using the ImmunoCard Mycoplasma test system. 2. Review of the Mycoplasma pneumoniae quality control and patient testing records showed that the laboratory included and documented the positive control material each day patient testing. The laboratory did not include a negative control material, when the following test kits were used: a. Lot. 7090U319 / (2026-08-19) Used dates: August 4, 2025, through August 26, 2025 Patient specimens performed and reported: 18 b. Lot. 7865.1165/ (2026-11-05) Used dates: November 4, 2025, through June 6, 2026 Patient specimens performed and reported: 169 c. Lot. 7848.1030 / (2027-07-09) Used dates: June 9, 2026, through July 27, 2026 Patient specimens performed and reported: 23 3. The laboratory performed and reported 210 of 210 Mycoplasma pneumoniae patient specimens from August 4, 2025, through July 27, 2026. 4. During interview, the Technical Consultant (CT) confirmed on August 5, 2026, at 1:55 p.m., that the laboratory includes positive control materials, but not a negative one.

D5469

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

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

This STANDARD is not met as evidenced by:
Based on a review of hematology quality control (QC) records (years 2025 - 2026) for the Cell-Dyn Emerald system and interview with the Technical Consultant (CT) on August 5, 2026, at 11:45 a.m., the laboratory failed to verify the manufacturer's stated values for the CELL-DYN 22 Plus Control Tri-Level hematology control materials before placing the new control lots into routine use. The laboratory processed and reported 2,914 of 2,914 Complete blood count (CBC) patient specimens from December 26, 2025, through August 4, 2026. The findings included: 1. Review of hematology quality control records, showed the laboratory used CELL-DYN 22 Plus Control Tri-Level hematology control materials to monitor CBC testing on the Cell-

Dyn Emerald system. 2. Review of QC records showed the laboratory placed the following lots of CELL-DYN 22 Plus Control materials into routine use without verifying the manufacturer's stated values: a. Control Lot number: L5349 (Low control), N5349 (Normal control) and H5349 (High control) Used dates: December 26, 2025, through February 25, 2026. Patient specimens processed and reported: 876 b. Control Lot number: L6040 (Low control), N6040 (Normal control) and H6040 (High control) Used dates: February 26, 2026, through April 17, 2026. Patient specimens processed and reported: 708 c. Control Lot number: L6096 (Low control), N6096 (Normal control) and H6096 (High control) Used dates: April 18, 2026, through June 15, 2026. Patient specimens processed and reported: 734 d. Control Lot number: L6152 (Low control), N6152 (Normal control) and H6152 (High control) Used dates: June 16, 2026, through August 4, 2026. Patient specimens processed and reported: 596 3. The laboratory processed and reported 2,914 of 2,914 Complete blood count (CBC) patient specimens from December 26, 2025, through August 4, 2026. 4. On August 5, 2026, at 11:56 a.m., the Technical Consultant (CT) confirmed during interview that the laboratory placed the CELL-DYN 22 Plus Control materials into routine use without first verifying the manufacturer's stated values.

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:

Based on human chorionic gonadotropin (hCG) test quality control records review (years 2024 -2026), hCG new lot reactivity verification records and Technical Consultant (CT) interview on August 5, 2026, at 1:03 p.m., the laboratory failed to evaluate new lots of hCG test kits for positive and negative reactivity before placing them into routine use. The laboratory performed and reported 79 out of 79 hCG patient specimens from September 6, 2024, through August 1, 2026. The findings include: 1. The laboratory performed qualitative hCG testing using different test kits from September 2024 to August 2026. The hCG quality control records and new - lot reactivity verification records were requested. (Revised on August 5, 2026, at 1:03 p. m.) 2. The hCG quality control test records and hCG test verification of new lot reactivity records were reviewed from September 2024, through August 1, 2026. Review of the hCG quality control records and new-lot reactivity verification worksheets showed that the laboratory failed to evaluate the following new lots for positive and negative reactivity before placing them into routine use: (Revised on August 5, 2026, at 1:07 p.m.) a. AimStep Combo Pregnancy (lot 22016 / 2025-01-31) Used dates: September 6, 2024, through November 22, 2024. Patient specimens performed and reported: 5 b. Alere hCG (Lot 0000953985/ 2027-01-01) Used dates: January 14, 2026, through May 18, 2026. Patient specimens performed and reported: 63 c. AllTest Pregnancy Rapid Combo (Lot ATHCG 26010020/ 2028-01-22) Used dates: June 9, 2026, through August 1, 2026. Patient specimens performed and reported: 11 3. The laboratory performed and reported 79 out of 79 hCG patient specimens from September 6, 2024, through August 1, 2026. 4. The Technical Consultant (CT) confirmed on August 5, 2026, at 1:24 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.
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. This STANDARD is not met as evidenced by: Based on review of white blood cells (WBC) manual differential comparison records (year 2025 - 2026), patient testing records and interview with the Technical Consultant (CT) on August 5, 2026, at 10:55 a.m., the laboratory failed to evaluate and define, twice a year, the relationship between WBC differential results obtained by the manual microscopic examination method and the Cell-Dyn Emerald system. The laboratory processed and reported 4,924 out of 4,924 Complete Blood Count (CBC) patient tests from July 2025 through August 4, 2026. The findings include: 1. The laboratory performed and reported WBC differential testing using two methods: manual microscopic examination and the Cell-Dyn Emerald system. The laboratory review and report only mature WBC. 2. On August 5, 2026, at 10:55 a.m., the WBC differential comparison records for the year 2025 and 2026 were requested. No records were available to demonstrate that the laboratory performed the required twice-yearly comparison between WBC differential results obtained by the manual microscopic examination method and the Cell-Dyn Emerald system. 3. Review of the patient testing records showed that the laboratory processed and reported 4,924 out of 4,924 CBC patient tests from July 2025 through August 4, 2026. 4. During interview on August 5, 2026, at 11:00 a.m., the Technical Consultant (CT) confirmed that the laboratory did not perform or document twice a year evaluation of the relationship of the WBC differential results between the manual method and the Cell-Dyn Emerald system.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of performance verification records (year 2025), proficiency testing records (year 2025), quality control records (years 2024 - 2026), the laboratory's procedure manual, and interview with the Technical Consultant (CT) on August 5, 2026, at 2:30 p.m., the laboratory director failed to fulfill the responsibilities and duties to ensure compliance with the quality control requirements for Complete Blood Count (CBC), White Blood Cell (WBC) 5-Parameter, human chorionic gonadotropin (hCG), and Mycoplasma pneumoniae IgM testing. Refer to: D6013, D6018, D6020, and D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the Cell-Dyn Emerald performance verification records (year 2025) and interview with the Technical Consultant (CT) on August 5, 2026, at 11:30 a.m., the laboratory director failed to review, evaluate and sign the data obtained during the performance verification of the Cell-Dyn Emerald instrument performed in July 2025. The findings include: 1. Review of the Cell-Dyn Emerald performance verification records showed that the laboratory director (LD) did not evaluate the obtained data. The records showed that the space provided for the LD signature was in blank. 2. The laboratory processed and reported 4,924 out of 4,924 CBC patient tests from July 2025 through August 4, 2026. 3. During interview, the Technical Consultant (CT) confirmed on August 5, 2026, at 12:50 p.m., that the completed Cell-Dyn Emerald performance verification records had not been signed, not evaluated by the LD.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) 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; and This STANDARD is not met as evidenced by: Based on review of Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 - 2026), Hematology proficiency testing (PT) scores (year 2025), and interview with the Technical Consultant (CT) on August 5, 2026, at 2:30 p.m., the laboratory director failed to ensure that proficiency testing reports with artificial scores were reviewed and evaluated to assess the laboratory's performance and identify problems requiring corrective action. Refer to: D5215.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 review of human chorionic gonadotropin (hCG), Mycoplasma pneumoniae, and hematology quality control records and interview with the Technical Consultant (CT) on August 5, 2026, at 2:30 p.m., the laboratory director failed to ensure that the laboratory established and maintained a quality control program that assured the quality of laboratory services provided. Refer to: D5403, D5449, D5469, D5471 and D5775.

D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the Technical Consultant (CT) on August 5, 2026, at 2:30 p.m., the Laboratory Director (LD) failed to ensure that an approved written procedure for Mycoplasma pneumoniae IgM testing was available to personnel responsible for the testing process. Refer to: D5401.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 review of human chorionic gonadotropin (hCG), Mycoplasma pneumoniae, and hematology quality control records and interview with the Technical Consultant (CT) on August 5, 2026, at 2:30 p.m., the Technical Consultant failed to establish a quality control program appropriate for the testing performed, establish parameters for acceptable levels of analytic performance, and ensure that these levels were maintained throughout the testing process for hCG, Mycoplasma pneumoniae, and Complete Blood Count (CBC) testing. Refer to D5449, D5469, and D5471.