Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1095984	04/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Irizarry Guasch Miradero	Carretera 108 Km 2 Hm 9 Barrio Miradero, Mayaguez, 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
D2127	HEMATOLOGY CFR(s): 493.851(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing Program (PRPTP) records, CASPER report 155, laboratory proficiency testing records review and interview with the laboratory supervisor #1 on April 29, 2025, at 9:50 A. M; it was determined that the laboratory failed to return the hematology proficiency testing results, for the second testing event of year 2024, within the time frame specified by PRPTP. The findings include: 1. The CASPER report 155 were reviewed before recertification survey date and showed that the laboratory obtain 0 percent in the hematology (complete blood cell , partial thromboplastin time, prothrombin time) in the second testing event of the year 2024. 2. The PRPTP records were reviewed on April 29, 2025, at 9:50 A,M and showed that the laboratory obtain 0 percent in the hematology in the second testing event of the year 2024. 3. Also, the records demonstrated that the laboratory failed to return the proficiency testing records within the time frame. 4. The laboratory supervisor #1 confirmed on April 29, 2025, at 10:15 AM that the laboratory failed to return proficiency testing results of hematology within the time frame specified by PRPTP in the second testing event of the year 2024. The laboratory processed and reported 20,654 hematology samples from march 2024 to June 2024.
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d) (d) Failure to return proficiency testing results to the proficiency testing program

	within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing Program (PRPTP) records, CASPER report 155, laboratory proficiency testing records review and interview with the laboratory supervisor #2 on April 29, 2025, at 12:29 P. M; it was determined that the laboratory failed to return the ABO group and D (Rho) typing proficiency testing results, for the second testing event of year 2024, within the time frame specified by PRPTP. The findings include: 1. The CASPER report 155 were reviewed before recertification survey date and showed that the laboratory obtain 0 percent in the ABO group and D (Rho) typing in the second testing event of the year 2024. 2. The PRPTP records were reviewed on April 29, 2025, at 12:15 P.M., and showed that the laboratory obtain 0 percent in the hematology in the second testing event of the year 2024. 3. Also, the records demonstrated that the laboratory failed to return the proficiency testing records within the time frame. 4. The laboratory supervisor #2 confirmed on April 29, 2025, at 12:29 P.M., that the laboratory failed to return proficiency testing results of ABO group and D (Rho) typing within the time frame specified by PRPTP in the second testing event of the year 2024. The laboratory processed and reported 1,063 ABO group and D (Rho) samples from march 2024 to June 2024.
D2164	UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(a) (a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing Program (PRPTP) records review, CASPER report 155 and interview with the laboratory supervisor #2 on April 29, 2025 at 12:29 PM; it was determined that the laboratory failed to attain an overall testing scores of 100 percent in unexpected antibody detection on the PRPTP in the first testing event of the year 2024. The findings include: 1. The CASPER report 155 were reviewed before the recertification survey date and showed that the laboratory obtain 80 percent in the unexpected antibody detection in the second testing event of the year 2024. 2. The laboratory PRPTP records were reviewed on April 29, 2025 at 12:15 PM and showed that the laboratory obtain 80 percent in the unexpected antibody detection in the first testing event of the year 2024. 3. The laboratory supervisor #2 confirmed on April 29, 2025 at 12:29 PM that the laboratory failed to attain an overall testing scores of 100 percent in unexpected antibody detection on the PRPTP in the first testing event of the year 2024.
D2169	UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(c) (c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

	This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing Program (PRPTP) records, CASPER report 155, laboratory proficiency testing records review and interview with the laboratory supervisor #2 on April 29, 2025, at 12:29 P. M; it was determined that the laboratory failed to return the unexpected antibody detection proficiency testing results, for the second testing event of year 2024, within the time frame specified by PRPTP. The findings include: 1. The CASPER report 155 were reviewed before recertification survey date and showed that the laboratory obtain 0 percent in the unexpected antibody detection in the second testing event of the year 2024. 2. The PRPTP records were reviewed on April 29, 2025, at 12:15 P.M., and showed that the laboratory obtain 0 percent in the unexpected antibody detection in the second testing event of the year 2024. 3. Also, the records demonstrated that the laboratory failed to return the proficiency testing records within the time frame. 4. The laboratory supervisor #2 confirmed on April 29, 2025, at 12:29 P.M., that the laboratory failed to return proficiency testing results of unexpected antibody detection within the time frame specified by PRPTP in the second testing event of the year 2024. The laboratory processed and reported 372 unexpected antibody detection samples from march 2024 to June 2024.
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 Puerto Rico Proficiency Testing Program (PRPTP) records review (2024-2025) and laboratory general supervisor (# 1) interview on April 29, 2025 at 10:00 AM, it was determined that the laboratory failed to verify the accuracy of the hematology specialty when the laboratory failed to report the proficiency testing results within the time frame established by the program. The findings include: 1. Puerto Rico Proficiency testing records were reviewed from February 2024 to April 2025, showing that the laboratory did not submit the PT results during the second testing event for year 2024. 2. The laboratory did not verify the accuracy of the hematology tests in the second testing event of year 2024. 3. The general supervisor # 1 confirmed on April 29, 2025 at 10:10A.M., that the laboratory did not verify the accuracy of these tests.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of the sample collection procedure manual, laboratory internal sample and received form and interview with the general supervisor # 1 and # 2 , it was determined that the laboratory did not follow their written instructions, regarding sample storage conditions of the referred from other labs. The findings include: 1. Review of the procedure manual (page 71-73) showing that the patient's samples for routine chemistry, endocrinology, inmunology the required storage condition was refrigerated samples . (2C-8C) 2. The laboratory document titled " Internal sample send and received form" showed that the laboratory requested to transport all patientsamples within 15C-25C. 3. Review, at random, of the documentation included in the " Internal sample send and received form" show that on 2/8/25, 2/20/25,, 2/21 /25, 2/22/25 an 2/27/25, showed that a total of 1,250 samples were transport between 15C-25C, regardless of the analyte to be processed. 4. The general supervisor # 1 and 2 confirmed on April 29, 2025 at 1:30 p. .m., that the laboratory did not follow their written instructions, regarding sample storage conditions of the referred from other labs.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on bacteriology control procedures worksheet for methicillin resistant staphylococcus aureus (MRSA) media, certificate of analysis records reviewed and interview with the laboratory supervisor #2 on April 29, 2025 at 9:58 AM; it was determined that the laboratory failed to check the ability to support growth of the new lot media of MRSA before or concurrent with the initial use. The laboratory processed and reported nine (9) patients sample from November 1, 2024 to November 6, 2024. The findings include: 1. The control procedures worksheet was reviewed on April 29, 2025 at 9:39 AM and showed that the laboratory performed the control procedures for MRSA media weekly. 2. The laboratory has the lot 639693 with expiration date of November 25, 2024. This lot was received on October 8, 2024 and was put in use on November 1, 2024. The worksheet record of control procedures showed that the laboratory did not performed the verification of the ability to support growth of the MRSA media until November 6, 2025. 3. The laboratory supervisor #2 confirmed on April 29, 2025 at 9:58 AM, that the laboratory failed to check the ability to support growth of the new lot media of MRSA before or concurrent with the initial use. The laboratory processed and reported nine (9) patients sample from November 1, 2024 to November 6, 2024.
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 (PRPTP) records, CASPER report 155 review and interview with the laboratory supervisor #1 and # 2 on April 29, 2025, at 9:50 A. M; it was determined that the laboratory director failed to ensure the return of the hematology, ABO group , D (Rho) typing and unexpected antibody detection proficiency testing results, for the second testing event of year 2024, within the time frame specified by PRPTP. Refer to D2127, D2159 and D 2169.
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 sample collection procedure manual, laboratory internal sample and received form, MRSA media quality control record, and interview with the laboratory supervisor #1 and #2 on April 29, 2025 at 1:20 P.M.; it was determined that the laboratory director did not assure that the laboratory follow the procedure manual established. Refer to D5311, D5477. .
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing program, sample collection procedure manual, bacteriology control procedures and interview with the laboratory supervisor #1 and #2 on April 29, 2025 at 1:40 P.M.; it was determined that the laboratory supervisor #1 and #2 failed to carry out successful day to day supervision in the different areas of the laboratory. Refer to D2127, D2159, D2164, D2169, D5215, D5311, D5477.