Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0667634	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Teresita	Calle Tomas Jordan #5, Utuado, 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	An announced CLIA Recertification survey was conducted at the Laboratorio Clnico Teresita on December 4, 2024 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on December 4, 2024, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 General Immunology 42 CFR 493.1403 Laboratory Director, Moderate Complexity Testing
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2023-2024) , Casper Report # 155 and laboratory director interview on December 4, 2024 at 10:20 A..M., it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from February 2023 to November 2024. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 % in white blood cell (WBC) analyte in the first testing event performed in March 2024. No remedial actions were taken. 3. The laboratory director confirmed on December 4, 2024 at 10:20 A.M. , that

	the laboratory failed to take remedial actions when obtained unsatisfactory results of 60 % in white blood cell (WBC) analyte in the first testing event performed in March 2024.
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 (year 2023-2024) , patient records review (year 2023-2024) and interview with the laboratory director on December 4, 2024 at 11:20 A.M., it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. Refer to D5449.
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: 1. Based on Quality Assessment (QA) written procedures review and laboratory director interview on December 4, 2024 at 9:45 AM, it was determined that the laboratory failed to follow the written procedures to ensure the positive identification and optimum integrity of patient specimen from the time of collection or receipt through completion of testing and reporting of results. The findings include: a. The laboratory QA written procedures establishes that the optimum integrityand patient identification must be evaluated with each event that occurs , and annually. b. The laboratory did not evaluate any situations related to specimen integrity nor patient identification since December 2023. vent that occurs with each plebotomist personnel since December 2023. c. The laboratory director confirmed on December 4, 2024 at 9: 47 A.M. thta the laboratory failed to follow the QA written procedures. 2. Based on Quality Assessment (QA) written procedures review (year 2023-2024) and laboratory director interview on December 4, 2024 at 9:48 A.M., it was determined that the laboratory failed to follow the written procedures to document and evaluate any complaint submitted and problems reported. The findings include: a. Quality Assessment (QA) records were reviewed since January 2024. b. The laboratory QA written procedures establishes that the laboratory must evaluated and documented evey month if any complaint was received. c.The laboratory did not evaluate nor document any complaint or problems since March 2024 d. The laboratory director confirmed on December 4, 2024 at 9:50 AM., that the laboratory did not follow the written procedures to document and evaluate any complaint submitted and problems reported.
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) written procedure review (year 2023-2024) and interview with the laboratory director interview on December 4, 2024 at 9:51 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests The findings include: 1. Review of the quality assessment program showed that evaluations to patient test request must be evaluated every six month. 2. Review of the quality assessment records showed that the last evaluation to patient test requests was performed in February 2023. 3. The laboratory director confirmed on December 4, 2024 at 9:53 A.M. that laboratory failed to perform the evaluations to test requests since February 2023.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae test quality control records review , patient results worksheet (years 2024) , laboratory testing personnel and laboratory director interview on December 4, 2024 at 11:15 , it was determined that the laboratory did not include an external positive and negative control material each day of use for Mycoplasma pneumoniae when 470 out of 470 patient specimen were processed and reported since January 2024. The findings include: 1. Mycoplasma pneumoniae test quality control records were review from January 2024 to December 3, 2024. 3. Review of Mycoplasma pneumoniae quality control records and patient results worksheet showed that the laboratory did not include any control material each day of patient testing since January 2024. 4. The laboratory processed and reported 470 Mycoplasma pneumoniae test since January 2024. 5. The laboratory director confirmed on December 4, 2024 at 11:15 A.M, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test. 6. This deficiency was cited in the last survey performed on March 31, 2023.
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: 1. Based on quality assessment (QA) records review (year 2023-2024) , laboratory director supervisor interview on December 4, 2024 at 9:57 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: a. Review of the laboratory quality assessment records showed that the laboratory established a monthly assessment for each analytic process to keep track the laboratory performance. b. Since January 2024, the quality assessment (QA) records showed that the laboratory did not perform the monthly evaluation of each analytic system. c. The laboratory director confirmed on December 4, 2024 at 9:58 A.M. , that the laboratory failed to perform the monthly evaluation of the analytic system. 2. Based on review of quality assessment (QA) records and laboratory director interview on December 4, 2024 at 10:07 A.M., it was determined that the laboratory failed to follow the written procedures to monitor and evaluate patient tests results for inconsistencies with patient information. The findings include: a. The quality assessment records were review from year 2023-2024. b. The QA manual included a page that instructed the laboratory to record any patient results which showed any inconsistency related to diagnosis, age, sex or other relevant results. c. The were no record of any test inconsistency since August 2023. d. The laboratory director confirmed on December 4, 2024 at 10:08 A.M. that information regarding test inconsistencies were not documented as established in the QA procedure manual. 3. Based on Quality Assesment (QA) written procedures review (2023-2024) and laboratory director interview on December 4, 2024 at 10:09 A.M., it was determined that the laboratory failed to evaluate the adecuacy of the system records. The findings include: a.The laboratory QA written procedures establishes that the adecuacy of the worklist or system records must be evaluated twice a year. b. On December 4, 2024 the QA written procedures were reviewed and it was determined that the laboratory failed to evaluate the adecuacy of the system record since December 2023. c. The laboratory director confirmed on December 4, 2024 at 10:09 A.M. that the laboratory failed to evaluate the adecuacy of the system records since 2023.
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 (QA) procedure manual, QA assessment records review (year 2023-2024) and interview with the laboratory director interview on December 4, 2024 at 10:10 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: turn around time and the patient's final test reports. The findings include: 1. Review of the quality assessment program showed that evaluations related to the laboratory turn around time and the patient's final test reports. must be evaluated each six month. 2. Review of the quality assessment record showed that the last turn around time and patient's final test reports evaluation was performed in February 2023. 3. The laboratory director confirmed on December 4, 2024 at 10:14 A.M., that the laboratory failed to perform the evaluations of turn around time and the patient's final test reports since February 2023.

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 Mycoplasma pneumoniae quality control records (2023-2024) QA Program review and laboratory director interview on December 4, 2024 at 11:20 A. M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements and the QA Program. Refer to D 6020 and D6021.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae quality records review (2023-2024) and laboratory director interview on December 4, 2024 at 11:25 AM, it was determined that laboratory director failed to ensure compliance with the requirements for Mycoplasma pneumoniae tests. Refer to D5449. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Quality Assessment records review (year 2023-2024) and laboratory director interview on December 4, 2024 at 12:00 P.M., it was determined that laboratory director failed to ensure compliance with quality assessment requirements. Refer to D5291, D5391, D5791 and D5891.
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 Mycoplasma pneumoniae quality control records review (2023-2024) and laboratory director interview on December 4, 2024 at 11:45 AM, it was determined that the laboratory testing personnel failed to ensure compliance with the requirements for Mycoplasma pneumoniae tests. The findings include: 1.The laboratory did not include an external positive and negative control material each day when reported and performed Mycoplasma pneumoniae test . Refer to D5449. 2. This deficiency was cited in the last survey performed on March 31, 2023.