Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2012865	08/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Jezer	Road 110 Km 10 Hm 6, Moca, 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
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 (year 2021-2022) and laboratory general supervisor interview on August 30, 2022 at 12:15 p.m., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphillis serology tests. Refer to D 5405.
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 (year 2021-2022) and interview with the laboratory supervisor on August 30, 2022 at 12:15 P.M, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. 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
D5201	CONFIDENTIALITY OF PATIENT INFORMATION

	CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on Quality Assessment records, written procedures review (year 2021-2022) and laboratory general supervisor interview on August 30, 2022, it was determined that the laboratory failed to follow written procedures to ensure confidentiality of patient information. The findings include: 1. Quality Assessment records were reviewed since January 2021 (review on August 30, 2022 at 9:40 a.m.) 2. The laboratory Quality Assessment written procedures establishes that the laboratory perform each six month an evaluation of confidentiality of patient information throughout all phases of the total testing process. (review on August 30, 2022 at 9:42 a.m.) 3. The laboratory did not perform an evaluation to ensure confidentiality of patient information since 7/16/2021. (review on August 30, 2022 at 9:43 a.m.) 4. The laboratory general supervisor confirmed on August 30, 2022 at 10:30 AM., that the laboratory did not perform an evaluation to ensure confidentiality of patient information since 7/16/2021.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review , written procedures review (year 2021-2022) and laboratory general supervisor interview on August 30, 2022, 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: 1. Quality Assessment (QA) records were reviewed since January 2021. (review on August 30, 2022 at 9:45 a.m.) 2. The laboratory QA written procedures establishes that the laboratory evaluated and documented monthly if had any complaint or problems. (review on August 30, 2022 at 9:45 a.m.) 3. The laboratory did not perform an evaluation nor document any complaint or problems since December 2021. (review on August 30, 2022 at 9:48 a.m.) 4. The laboratory general supervisor confirmed on August 30, 2022 at 10:30 AM., that the laboratory did not follow the written procedures to document and evaluate any complaint submitted and problems reported.
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) records , QA written procedures review (year 2021-2022) and laboratory director and laboratory general supervisor interview on August 30, 2022 at 12:00 P.M. it was determined that laboratory failed to monitor and evaluate the following QA activities: Confidentiality and Complaint investigations. Refer to D5201 and D5205.
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 procedure manual, quality assessment (QA) records review (year 2021-2022) and interview with the laboratory general supervisor interview on August 30, 2022, 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. (review on August 30, 2022 at 9:50 a.m.) 2. Review of the quality assessment records showed that the last evaluation to patient test requests was performed in June 30, 2021.(review on August 30, 2022 at 9:50 a.m.) 3. The laboratory director confirmed that evaluations to patient test requests was not performed since June 2021. (review on August 30, 2022 at 9:55 a.m.)
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 syphillis serology quality control review (year 2021-2022) and laboratory general supervisor interview on August 30, 2022 , it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by RPR card test ASI method. The findings include: 1. The syphillis sorology quality control records were reviewed since January 2021. (review on August 30, 2022 at 11:15 a.m.) 2. The manufacturer's instruction establishes that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. (review on August 30, 2022 at 11: 17 .m.) 3. Review of records from January 2021 to August 2022 showed that the laboratory did not include control material the following days: (review on August 30, 2022 at 11:20 a.m.) date patient identification 7/19/2022 71285, 71280 7/20/2022 71321, 71305 7/22/2022 71419, 71420 7/26/2022 71488 7/27/2022 71555 7/28/2022 71578 8/2/2022 71722 8/6/2022 71914 8/8/2022 72031 8/9/2022 72094, 72087 4. The

	general supervisor confirmed on August 30, 2022 at 12:10 p.m. that the laboratory did not include the three levels of control material (non reactive, minimal to moderate and reactive) those days.
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 General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2021-2022) and laboratory general supervisor interviewon August 30, 2022 , it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. The findings include: 1. The laboratory performed Mycoplasma Pneumoniae test by Immuno Card method.(review on August 30, 2022 at 11:30 a.m.) 2. General Immunology (Mycoplasma pneumoniae test) quality control records were review on January 2021 to August 30, 2022. (review on August 30, 2022 at 11:35 a.m.) 2. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include positive and negative control material each day of patient testing since January 2021.(review on August 30, 2022 at 11:37 a.m.) 3.The laboratory reported and performed 291 Mycoplasma pneumoniae test in year 2021 and 350 in 2022.(review on August 30, 2022 at 11:45 a.m.) 4. The laboratory general supervisor confirmed on August 30, 2022 at 12:15 P.M, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test.
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 2021-2022) , laboratory general supervisor interview on August 30, 2022 at 10:00 AM, 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 establishes a monthly assessment for each analytic process to keep track the laboratory performance. (review on August 30, 2022 at 10:05a.m.) b. Since December 2021, the quality assessment (QA) records showed that the laboratory did not perform the monthly evaluation of the analytic system. (review on August 30, 2022 at 10:10a.m.) c. The laboratory director confirmed on August 30, 2022 at 12:00 P.M., that the laboratory failed to perform the monthly evaluation of the analytic system. 2. Based

	on quality assessment (QA) written procedures, QA records review (year 2021-2022) and interview with the laboratory general supervisor interview on August 30, 2022 at 10:20 a.m., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: comparison of test results. The findings include: a. The laboratory performed and reported white blood cells differential counts by the Sysmex system and also performed manual slide screenings. b. Review of the quality assessment records, showed that evaluations related to comparison of test results (white blood cell differential count) must be evaluated every six months records. (review on August 30, 2022 at 10:22 a.m.) c. The quality assessment record showed that the last evaluation was performed in December 29, 2021 (review on August 30, 2022 at 10: 25a.m.) d. . The laboratory director confirmed on August 30, 2022 at 12:00 P.M., that the laboratory failed to perform the evaluations of comparison test results.
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 2021-2022) and interview with the laboratory general supervisor interview on August 30, 2022, 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. The evaluations and findings , if any, must be documented in the QA records.(review on August 30, 2022 at 10:30a.m.) 2. Review of the quality assessment record showed that the last turn around time and patient's final test reports evaluation was performed on May 2020 and October 12, 2020 , respectively. (review on August 30, 2022 at 10:30a.m.) 3. The laboratory director confirmed on August 30, 2022 at 12:00 P.M., that the laboratory failed to perform the evaluations of turn around time and the patient's final test reports since 2020.
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 syphilis serology, general immunology quality control , quality assessment records review (year 2021-2022) and laboratory director interview on August 30, 2022 at 12:15 P.M., 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 D 6093 and D 6094.

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 review (year 2021-2022) and laboratory director interview on August 30, 2022 at 12:15 p.m, it was determined that laboratory failed to ensure compliance with the requirements for syphilis serology and general immunology analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by RPR card test ASI method. (Refer to D5405) 2. The laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. (Refer to D5449)
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 Assessment (QA) records review (year 2021-2022) and laboratory director interview on August 30, 2022 at 12:15 P.M., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records (2021-2022) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. (review on August 30, 2021 at 9:40a.m.) 2. The laboratory director confirmed on August 30, 2022 at 12:15 p.m. , that failed to evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. Refer to D5291 , D5391, D5791 and D5891.
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 syphilis serology , Mycoplasma pneumoniae test quality control records review (year 2021-2022) and laboratory general supervisor interview on August 30, 2022 at 12:10 p.m, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by RPR card test ASI method. (Refer to D5405) 2. The laboratory did not include an external positive and negative

	control material each day of Mycoplasma pneumoniae patient testing. (Refer to D5449)