Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658123	09/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Universal	Calle Munoz Rivera 56 Suite 1, Juncos, 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
D2072	SYPHILIS SEROLOGY CFR(s): 493.835(d) (1) For any unsatisfactory 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 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 (PRPTP) records review from February 2020 to June 2021 and laboratory director interview on September 14, 2021 at 9:35 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in syphilis serology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were reviewed since February 2020 to June 2021. 2. Review of proficiency testing (PRPTP) records showed that the laboratory obtained unsatisfactory results of 0 percent in syphilis serology (qualitative) and syphilis serology (quantitative) tests in December 2020 (PRPTP third testing event). No remedial actions were taken. 3. The laboratory director confirmed on September 14, 2021 at 9:35 AM, that the laboratory did not take corrective actions on December 2020 testing event.
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 general immunology (Mycoplasma pneumoniae) quality control records review from January 21, 2021 to September 13, 2021 and laboratory director interview on September 14, 2021 at 11:05 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of General Immunology. The finding includes: 1. The laboratory did not include each day of testing a negative and a positive control materials when patients serum specimens were tested for qualitative Mycoplasma by the Immuno Card Mycoplasma method. Refer to D 5449.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 quality control records review from January 4, 2021 to September 13, 2021, procedures manual review and laboratory director interview on September 14, 2021 at 10:48 AM, it was determined that the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, voltage and refrigerator and freezer temperatures. The findings include: 1. The laboratory procedures manual established that the laboratory must monitor and document daily the room temperature, relative humidity, voltage, refrigerator and freezer temperatures. 2. The records showed that the laboratory did not monitor nor document the room temperature, relative humidity and voltage. Also did not documented the refrigerator and freezer temperatures when test kit and reagents were stored. 3. Monitoring of the laboratory temperature, humidity and voltage are crucial for the reagents used in the laboratory. 4. The laboratory director confirmed on September 14, 2021 at 10:48 AM, that the laboratory did not monitor nor document the laboratory's room temperatures, relative humidity, voltage, refrigerator and freezer temperature since January 4, 2021.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on lack of the records for the verification of the performance specifications for the new hematology instrument (Mindray) and interview with the laboratory director on September 14, 2021 at 10:48 AM, it was determined that the laboratory failed to verify the Mindray hematology performance specifications, prior to use it with patients samples. The findings include: 1. The laboratory began to use the Mindray hematology system on April 24, 2021. 2. There were no records of the data used to verify the parameters nor the performance specifications (precision, comparison test, manufacturer's reference intervals), prior to April 24, 2021. 3. The laboratory director confirmed on September 14, 2021, that the laboratory did not perform the evaluation of the performance specifications of the Mindray system. 4. The laboratory processed and reported 3,480 hematology patient's samples (CBC) from April 24, 2021 to September 14, 2021.
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 from January 1, 2021 to September 13, 2021 and interview with the laboratory director on September 14, 2021 at 11:05 AM, it was determined that the laboratory failed to include a negative and positive control material when performed Mycoplasma pneumoniae test by Immuno Card method. The findings include : 1. The laboratory performed Mycoplasma pneumoniae test by Immuno Card method. 2. Review of the Mycoplasma pneumoniae quality control records, showed that the laboratory did not include a negative and positive control material each day of testing in eight (8) out of 48 patients specimens processed from January 21, 2021 to September 13, 2021. 3. The laboratory did not included a negative and positive control material on July 21, 2021 (two (2) patients specimens), August 2, 2021 (two (2) patient specimens), September 10, 2021 (two (2) patient specimens), September 11, 2021 (one (1) patient specimen) and September 13, 2021 (one (1) patient specimen). 4. The laboratory director confirmed on September 14, 2021 at 11:05 AM, that the laboratory failed to include a negative and positive control material in these day of testing when performed Mycoplasma pneumoniae test. 5. This deficiency was cited on October 11, 2019.
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) records review from January 2019 to September 14, 2021 and laboratory director interview on September 14, 2021 at 10:36 AM, it

	was found that the laboratory did not evaluate the following aspect included in the QA laboratory program (Turn Around Time). The findings include: 1. The laboratory QA program was reviewed on September 14, 2021 at 10:36 AM. The laboratory program established that the evaluation of the turn around time (TAT) must be done every year. 2. Review of the laboratory QA program for the year 2019, 2020 and 2021, showed that the laboratory did not evaluate the laboratory turn around time (TAT) since January 2020. 3. The laboratory director confirmed on September 14, 2021, that the laboratory did not evaluate the turn around time (TAT) since January 2020. 4. This deficiency was cited on October 11, 2019.
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 proficiency testing records review, quality control records review and laboratory director interview on September 14, 2021 at 11:05 AM, 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 D6018, D6020 (1), (2) and D6021.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that 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; This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2020 to June 2021 and laboratory director interview on September 14, 2021 at 9:40 AM, it was determined that the laboratory director failed to ensure that corrective actions were documented when the laboratory failed to obtain an acceptable participation for syphilis serology tests. Refer to D2072 (did not take nor document a corrective actions for syphilis serology tests during the PRPTP third testing event of year 2020). .
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: 1. Based on general immunology (Mycoplasma pneumonia) quality control records review from January 21, 2021 to September 13, 2021 and interview with the laboratory director on September 14, 2021 at 11:05 AM, it was determined that the laboratory director failed to ensure that external , negative and positive control material, were included by the testing personnel each day of Mycoplasma pneumoniae patient testing. The finding includes: a. The laboratory did not include a positive and a negative control material when performed Mycoplasma pneumoniae each day of patient testing. Refer to D5449. 2. Based on quality control records review from January 2020 to September 14, 2021 and laboratory director interview on September 14, 2021 at 11:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: a. The laboratory director did not assure that the laboratory: a. monitor and document the laboratory's room temperature, relative humidity, voltage and refrigerator and freezer temperatures. Refer to D5413. b. to perform the evaluation of the performance specifications of the Mindray hematology system. Refer to D5423.
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 (QA) records review and laboratory director interview on September 14, 2021 at 11:45 AM, it was determined that laboratory director failed to ensure compliance with quality assessment requirements. The finding includes: 1. The laboratory did not evaluate the following aspect included in the QA laboratory program (Turn Around Time). Refer to D5891.