Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0927289	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Marie E	Carr 862 Km 2-7 63b Victoria Heights, Bayamon, 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
D2082	GENERAL IMMUNOLOGY CFR(s): 493.837(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 (PRPTP) records review (year's 2016, 2017 and 2018) and laboratory director interview on May 3, 2018 at 9:25 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in general immunology serology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to February 2018. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Antistretolysin O (ASOT - qualitative) tests in December 2016 (PRPTP third testing event) and 40 percent in Helicobacter pylori tests in April 2017 (PRPTP first testing event). No remedial actions were taken.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(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: 1. Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (year's 2016, 2017 and 2018) and laboratory director interview on May 3, 2018 at 9:25 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: a. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to February 2018. b. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 40 percent in Sodium (Na+) in February 2017 (PRPTP first event). No remedial actions were taken. 2. Based on American Association of Bioanalysts ProficiencyTesting Program (AAB) records review and laboratory director interview on May 3, 2018 at 9:25 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: a. American Association of Bioanalysts ProficiencyTesting Program records and results were reviewed since January 2016 to April 2018. b. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 50 percent in Uric Acid - urine chemistry (AAB third quarterly testing event 2016) and 0 percent in Urea Nitrogen (BUN) - urine chemistry (AAB first quartely testing event 2017). No remedial actions were taken.
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 laboratory procedures manual, laboratory quality control records review (year's 2016, 2017 and 2018) and laboratory testing personnel and laboratory director interview on May 3, 2018 at 10:23 AM, it was determined that the laboratory failed to monitor and document the laboratory's room temperature and relative humidity in the bacteriology area. The findings include: 1. The laboratory procedures manual establishes that the laboratory monitor and document daily the room temperature and relative humidity. 2. From January 4, 2016 to May 3, 2018, the laboratory did not monitor and document the daily the room temperature and relative humidity. 3. The laboratory records showed that the laboratory working 705 days from January 4, 2016 to May 3, 2018 (2016 - 305 days, 2017 - 297 days and 2018 - 103 days). 4. The laboratory director confirmed on 05/03/2018, that the laboratory did not monitor and document the room temperature and relative humidity those days.
D5479	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review (year's 2017 and 2018) and laboratory director and testing personnel interview on May 3, 2018 at 10:21 AM, it was determined that the laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Monocolex method. The findings include: 1. The Monocol/lex manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 saline dilution due to a prozone phenomena. 2. From January 2, 2017 to May 2, 2018, the Mono quality control records showed that the laboratory did not check 8 out of 8 patient's specimens at a 1:10 dilution before it reported as negative Monotest on 02/17/2017, 04/13/2017, 05/17/2017, 07/17/2017, 08/09/2017, 10/20/2017, 01/10/2018 and 04/02/2018. 3. The laboratory director and testing personnel confirmed on May 3, 201, that the MONO testing records did not include the 1:10 dilution results recorded.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on laboratory procedures manual and bacteriology gram stain quality control records review (year's 2016, 2017 and 2018) and laboratory director and testing personnel interview on May 3, 2018 at 10:29 AM, it was determined that the laboratory was failed to check the Gram stain reactivity with control organism each week of use. The findings include: 1. The laboratory procedures manual established that the laboratory check the Gram stain reactivity with control organism each week of use. 2. The laboratory did not perform and document the check of the Gram stain reactivity each week of use from January 4, 2016 to May 3, 2018. 3. The laboratory records showed that the laboratory working 705 days from January 4, 2016 to May 3, 2018 (2016 - 305 days, 2017 - 297 days and 2018 - 103 days). 4. The laboratory director and the testing personnel confirmed on May 3, 2018, that the laboratory failed to follow the procedures to check the Gram stain each week of use from January 4, 2016 to May 3, 2018.
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: Based on quality assessment (QA) records review (year's 2016, 2017 and 2018) and laboratory director interview on May 3, 2018 at 9:42 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: 1. Review of the laboratory quality assessment manual showed that for each analytic process a log sheet was designate to keep track of the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic systems: a. to monitor and document the laboratory's room temperature and relative humidity in the bacteriology area. Refer to D5413. b. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Immuno/lex - IM method. Refer to D5479. c. to check the Gram stain reactivity with control organism each week of use. Refer to D5503.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: 1. Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (year's 2016, 2017 and 2018) and laboratory director interview on May 3, 2018 at 10:12 AM, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: a. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to February 2018. b. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Antistretolysin O (ASOT - qualitative) tests in December 2016 (PRPTP third testing event) and 40 percent in Helicobacter pylori tests in April 2017 (PRPTP first testing event). No remedial actions were taken. c. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 40 percent in Sodium (Na+) in February 2017 (PRPTP first event). No remedial actions were taken. d. The laboratory director confirmed on May 3, 2018, that the laboratory did not take corrective actions on those testing events. Refer to D2082 and D2094. 2. Based on American Association of Bioanalysts ProficiencyTesting Program (AAB) records review (year's 2016, 2017 and 2018) and laboratory director interview on May 3, 2018 at 9:25 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: a. American Association of Bioanalysts ProficiencyTesting Program records and results were reviewed since January 2016 to April 2018. b. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 50 percent in Uric Acid - urine chemistry (AAB third quarterly testing event 2016) and 0 percent in Urea Nitrogen (BUN) - urine chemistry (AAB first quarterly testing event 2017). No remedial actions were taken. c. The laboratory director confirmed on May 3, 2018, that the laboratory did not take corrective actions on those testing events. Refer to D2094.
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's 2016, 2017 and 2018), laboratory director and testing personnel interview on May 3, 2018 at 11:55 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to monitor and document the laboratory's room temperature and relative humidity in the bacteriology area. Refer to D5413. b. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Immuno /lex - IM method. Refer to D5479. c. to check the Gram stain reactivity with control organism each week of use. Refer to D5503.
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's 2016, 2017 and 2018), laboratory director and testing personnel interview on May 3, 2018 at 11:48 AM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requierements. The finding includes: 1. The laboratory did not evaluate the established Quality Asessment Program to monitor and evaluate the requirement for general and analytic systems. Refer to D5791.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high 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 quality control records review (year's 2016, 2017 and 2018), laboratory director and testing persnnel interview on May 3, 2018 at 11:58 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel failed the following quality control procedures: a. to monitor and document the laboratory's room temperature and relative humidity in the bacteriology area. Refer to D5413. b. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Immuno /lex - IM method. Refer to D5479. c. to check the Gram stain reactivity with control organism each week of use. Refer to D5503.