Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0692200	08/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico La Merced	Avenida Domenech Num 310, Hato Rey, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (year 2021-2022) and laboratory general supervisor interview on August 22, 2022 , it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2021 to July 2022. (review on August 22, 2022 at 11:09 a. m.) 2. The review of records showed that the laboratory director and laboratory general supervisor (testing personnel) did not sign the attestation statements of the Proficiency testing records from February 2021 to December 2021. (review on August 22, 2022 at 11:10 a.m.) 3. The laboratory general supervisor confirmed on August 22,2022 that the laboratory director and general supervisor (testing personnel) failed to sign the attestation statements in 2021. (review on August 22, 2022 at 11: 15a.m.)
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by:

	Based on bacteriology quality control records review from year 2021-2022 and interview with the laboratory director on August 22, 2022 at 2:10 p.m. it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology. The findings include: 1. The laboratory failed to follow written instructions for urine culture processing.. Refer to D5407. 2. The laboratory failed to check each batch of lot of Blood Agar / Mc Conkey biplate and chocolate culture media plates for its ability to support growth. and sterility. Refer to D5477.
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 syphilis serology quality control records review (year 2021-2022) and laboratory general supervisor interview on August 22, 2022 , it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method. The findings include: 1. 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 22, 2022 at 1:45 p.m.) 2. Syphilis serology quality control record were reviewed from January 2021 to July 2022. (review on August 22, 2022 at 1:47 p.m.) 3.The syphilis serology quality control records from May 16, 2022, showed that the laboratory did not include the three levels of control material when it processed and reported 2 out of 2 patients specimens for syphilis serology by RPR method (patients specimens # 13757 and # 137911). (review on August 22, 2022 at 1:55 p.m.) 4. The general supervisor confirmed that the laboratory failed to performed nor documented the quality control procedures those days (review on August 22, 2022 at 1:57 p.m.) .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on bacteriology procedure manual review , culture media quality control work sheet (year 2021-2022) and laboratory general supervisor interview on August 22, 2022, it was determined that the laboratory failed to failed to follow written instructions for urine culture processing. The findings include : 1.The bacteriology written procedure manual review stated that the laboratory use BA and McConkey agar media single plate to perform urine culture test, however, the culture media quality control work sheet showed that the laboratory uses BA/McConkey biplate agar media to perform this culture. (review on August 22, 2022 at 12:38 p.m.) 2. During the survey the laboratory general supervisor stated that the laboratory reported and processed 510 urine patient culture in 2021 and 227 urine culture in 2022. (review on August 22, 2022 at 12:42 p.m.) 3. During the survey on August 22, 2022 at 12:40 p.m

	the bacteriology culture media QC worksheet was reviewed. The document showed that the urine samples were inoculated in a BA/ Mc biplate , instead of single plates. 4. The laboratory general supervisor was not able to establish when the procedure was changed. (review on August 22, 2022 at 12:55 p.m.)
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verifications records reviewed (year 2021-2022) and laboratory general supervisor interview on August 22, 2022 , it was determined that the laboratory failed to perform at least ,every six months, the calibration verification procedures for the routine chemistry tests processed by the Selectra system. The findings include: 1. The laboratory uses Selectra system for routine chemistry tests (lipid panel and glucose test). 2. Review of routine chemistry calibration verification records from January 2021 to August 2022, showed that the laboratory did not perform the calibration verification procedures for routine chemistry tests schedule for December 17, 2021. No calibration verification procedures were performed during year 2022 neither. (review on August 22, 2022 at 1:35 p.m.) 3. The laboratory reported and processed 15 proficiency samples for routine chemistry subspecialty in 2022. (review on August 22, 2022 at 1:38 p.m.) 4. The laboratory general supervisor confirmed on August 22, 2022 at 1:45 p.m., that the laboratory failed to perform at least six months the calibration verification procedures for routine chemistry tests perform by the Selectra system since June 17, 2021.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on bacteriology quality control records review (year 2021-2022) and interview with the laboratory general supervisor on August 22, 2022 , it was determined that the laboratory failed to check each batch of culture media plates for sterility. The finding includes: a. The bacteriology quality control records showed that the laboratory did not check for sterility the following Blood Agar / Mc Conkey biplate agar media received during year 2021-2022: lot numbers - 479211, 483015, 485727, 488138P, 489418, 492447, 494189, 496308, 499811, 502427, 504410, 507360, 508553 and 509398P. (review on August 22, 2022 at 12:30 p.m.) b. The records showed that the laboratory did not check for sterility the following chocolate agar media plate received during year 2021: lot numbers - 499354 and 495836. (review August 22, 2022 at 12:40 p.m.) c. The laboratory reported and performed a total of 510 urine culture, 50 throat culture in 2021 and 227 urine culture and 34 throat culture in 2022. d. The laboratory general supervisor confirmed on August 22, 2022 at 12:50 p.m. that the laboratory failed to check each batch of Blood Agar / Mc Conkey biplate and chocolate culture media plates for sterility. 2. Based on bacteriology quality control records review (years 2021-2022) and interview with the laboratory general supervisor on August 22, 2022 , it was determined that the laboratory failed to check each lot of Blood Agar / Mc Conkey biplate and chocolate culture media plates for its ability to support growth. The finding includes: a. The laboratory performed urine colony count tests and performed primary inoculation on blood and Mac Conkey biplate agar. b. Review of bacteriology quality control records showed that the laboratory did not check the ability to support growth of the following lot numbers of BA / Mc Conkey biplate agar media used by them since February 25, 2021: 479211, 483015, 485727, 488138P, 489418, 492447, 494189, 496308, 499811, 502427, 504410, 507360, 508553 and 509398P. (review August 22, 2022 at 12:45 p.m.) c. Review of bacteriology quality control records showed that the laboratory did not check the ability to support growth of the following lot numbers of chocolate agar used by them since August 21, 2021: 499354 and 495836 (review August 22, 2022 at 12:47 p.m.) d. The laboratory processed 737 urine culture and 84 throat culture patient's samples from January 2021 to August 22, 2022. (review August 22, 2022 at 12:48 p.m.) e. The laboratory general supervisor confirmed on August 22, 2022 at 12: 50 p.m. that the laboratory failed to check each batch of Blood Agar / Mc Conkey biplate and chocolate culture media plates for its ability to support growth.
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 bacteriology quality control records review (year 2021-2022) and laboratory general supervisor interview on August 22, 2022 at 2:10 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the bacteriology quality control requirements. The finding

	includes: 1. The laboratory director did not ensure quality control procedures for bacteriology were implemented and followed. Refer to D6093
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 records review (years 2021-2022) and laboratory general supervisor interview on August 22, 2022 at 11:09 A. M, it was determined that the laboratory director failed to evaluate any problems relate to PT performance. The finding includes: 1. The laboratory director and testing personnel failed to sign the attestation statements. Refer to D2009. (review on August 22, 2022 at 11:30 a..m.)
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: 1. Based on review of bacteriology quality control records review (year 2021-2022) and interview with the laboratory director and laboratory general supervisor on August 22, 2022 at 2:10 p.m. , it was found that the laboratory director did not ensure quality control procedures for bacteriology were implemented and followed. The findings include: a. No quality control procedures for sterility not ability to support groth and sterility was performed. (Refer to D5477.) b. The laboratory director failed to follow written instructions for urine culture processing. (Refer to D5407) 2. Based on review of syphilis serology and routine chemistry qualiity control records review (year 2021-2022) and interview with the laboratory director and laboratory general supervisor on August 22, 2022 at 2:15 p.m. , it was found that the laboratory director did not ensure oversight that the establish quality control procedures for syphilis serology and routine chemistry were implemented and followed. The findings include: a. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method. Refer to D5405. b.The laboratory failed to perform at least every six months the calibration verification procedures for the routine chemistry tests processed by the Selectra system. Refer to D5439.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain

	their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on laboratory testing personnel record review (year 2021-2022) , observation , and laboratory technical supervisor interview on August 22, 2022, it was determined that the laboratory technical supervisor failed to assure that the testing personnel (MT # 2) received a training prior to begin to test patient samples. The findings include: 1. The laboratory testing personnel record showed that the medical technologist (MT # 2) started to work on August 2021. (review on August 22, 2022 at 12:07 p.m.) 2. During the survey the surveyor observed that the MT # 2 was performing Complete Blood Cell (CBC) test and Covid test. (review on August 22, 2022 at 12:10 p.m.) 3. The record showed that the technical supervisor failed to perform and document the required training of the MT. (review on August 22, 2022 at 12:07 p.m.) 4. The technical supervisor confirmed on August 22, 2022 at 12:15 p.m. did not perform no training not initial competence procedures were given to the new MT prior to test patient specimens for hematology and covid test.
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 bacteriology quality control records review (year 2021-2022) and laboratory general supervisor interview on August 22, 2022 at 2:00 P.M. , it was determined that the general supervisor failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method. Refer to D5405. 2. The laboratory failed to follow written instructions for urine culture processing.. Refer to D5407. 3 The laboratory failed to perform at least every six months the calibration verification procedures for the routine chemistry tests processed by the Selectra system. Refer to D5439. 4. The laboratory failed to check each batch of lot of Blood Agar / Mc Conkey biplate and chocolate culture media plates for its ability to support growth. and sterility. Refer to D5477.