Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0984583	06/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Caribbean Medical Center	Ave Osvaldo Molina #151 Carr 194, Fajardo, 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
D2026	BACTERIOLOGY CFR(s): 493.823(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) 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 P.R.Proficiency Testing Program records review and laboratory technical supervisor interview it was determined that the laboratory failed to take and document any corrective actions when it obtained an unsatisfactory results in bacteriology (gram stain) specialty. The findings include: 1. P.R. Proficiency Testing Program records and results were reviewed on June 14, 2022 at 9:43 am, from year 2021-2022. 2. Review of P.R. Proficiency Testing records showed that the laboratory obtain 0% in gram stain in the Bacteriology specialty. The laboratory did not take any corrective actions when obtained unsatisfactory results in Bacteriology specialty in the third event of 2021. 3. The laboratory technical supervisor confirmed on June 14, 2022 at 9: 50am that the laboratory did not take any corrective action in the third event of 2021 when obtain 0% in gram stain of the Bacteriology specialty
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory testing area and laboratory technical supervisor interview, it was determined that laboratory did not have enough space to carry out the handling of patient samples, space for documentation or report procedures performed by the testing personnel. The findings include: 1. It was observed on June 14, 2022 at 10:50 am that the laboratory space was crowded with instruments, computers, printers and materials. The testing personnel did not have space for specimen handling or documentation. 2. The laboratory technical supervisor confirmed on June 14, 2022 at 1:15 pm, that the testing area was very crowded and letting few space to perform the patient samples.
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 review of ASI C-Reactive Protein (CRP) slide test manufacturer's instructions, CRP testing records review (years 2020-2022) and technical supervisor interview on June 14, 2022 at 12:15 pm, it was determined that the laboratory failed to meet the requirements in the subspecialty of general immunology for CRP test. Refer to D5403, D5407, D5451, D5023 and D5787.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on General Immunology quality control review (year 2020-2022) laboratory C-Reactive Protein (CRP) written procedure, patient worklist and interview with the laboratory technical supervisor, it was determined that the laboratory did not include, the step by step instructions, on how to performed the 1:2 and 1:4 serial dilutions of

	those CRP samples that showed an initial negative reaction. The findings include: 1. The general immunology quality control records were reviewed on June 14, 2022 at 11:22am since January 1, 2020 to June 13, 2022. 2. The written procedures instructed to perform a 1:2 and 1:4 dilution to those samples that showed a negative result. The written instructions did not include how to perform the serial dilution. 3. The technical supervisor confirmed on June 14, 2022 at 11:29 am that the laboratory did not include the step by step of how to perform the serial dilution. 4. Review of the patient worklist (year 2020-2022) on June 14, 2022 at 11:24 am, showed that 1,914 out of 3,150 patient samples were diluted after an initial negative CRP result.
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 review of the C-Reactive Protein (CRP) procedure manual and interview with the laboratory technical supervisor, it was determined that the written procedure manual for general immunology was not signed by the laboratory director. The findings include: 1. During the review of the procedure manual on June 14, 2022 at 11: 31 am, it was found that the procedure manual was approved by the Hospital Adminitrator on June 25, 2021. 2. There was no evidence of approval by the laboratory director. 3. The technical supervisor confirmed on June 14, 2022 at 11: 35am, that the procedure manual was approved by the Hospital Administrator.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions (M.I), laboratory procedure manual, C-Reactive Protein (CRP) patient's test and quality control worklist and interview with the laboratory technical supervisor (MT #5309), it was determined that the laboratory introduced a modification to the CRP test manufacturer procedure without having established the performance specification, prior to report patient's test. The findings include: 1. Review on June 14, 2022 at 11:00 am the laboratory patient test and quality control worklist showed that the laboratory put in use the ASI CRP slide test on January 1, 2020. 2. Review of the CRP manufacturer's instructions on June 14, 2022 at 11:15 am, showed that the laboratory was instructed to: a. To allow reagents and samples to warm to room temperature (20-30C) before use. b. Dispense one fill-

	falling drop of each patient sample on the test card. c. Add one drop of the reagent to each serum specimen. d. Mix the specimen and reagent. e. Rotate the card for two (2) minutes and observe for agglutination. 3. Review of the laboratory written instructions for CRP on June 14, 2022 at 11:21 am, showed that a modified procedure was approved on June 25, 2021, effectivity date June 23, 2021. The reviewed CRP modified instructions established the following: a. To dispense a drop on the test card and spread. b. to rotate for two minutes at 100 rpm. c. to dilute all negative test results on a serial dilution of 1:2 and 1:4 and then report. d. Not to read the test reaction if more than four (4) minutes passed. 4. During the interview with the laboratory technical supervisor (also designee as supervisor and testing personnel) on June 14, 2022 at 11:47 am, she stated that the laboratory did not evaluate the performance specification of the CRP test when the laboratory modified the manufacturer's instructions. 5. The patients and quality control worklist reviewed on June 14, 2022 at 11:00 am, showed that since January 1, 2020 to June 13, 2022, the laboratory processed and reported 3,150 patient samples. 1,236 out of 3,150 were directly reported as positive ones. 1,914 out of 3,150 were reported initially negative and later diluted. 278 out of 1,914 were reported as negative (non diluted) and positive after a 1: 4 dilution. 6. Elevated levels of CRP are sensitive indicators of inflamation associated with the acute phases of rheumatic fever, rheumatoid arthritis, bacterial and viral infections.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on general immunology C-Reactive protein (CRP) testing records review from January 1, 2020 to June 13, 2022 and laboratory technical supervisor interview, it was determined that the laboratory failed to include, a negative control material and a control material with tittered reactivity when patients specimens were tested for CRP semiquantitative tests by ASI method. The findings include: 1. The laboratory uses ASI CRP slide test method to perform C Reactive Protein (CRP) patient's sample tests. 2. Review of records from January 1, 2020 to June 13, 2022 at 12:00 pm, the CRP testing records showed that the laboratory did not include, a negative control material and a control material with tittered reactivity when 1,914 out of 3,150 patients specimens were processed and reported for quantitative test from January 1, 2020 to June 13, 2022. 3. The laboratory processed and reported 278 CRP with tittered test result. 4. The laboratory technical supervisor confirmed on June 14, 2022 at 12:33pm, that the testing records showed that the laboratory did not perform nor document the semiquantitative control procedures those days.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time

	of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on testing records review of C-Reactive Protein (CRP) and interview with the laboratory technical supervisor, it was determined that the laboratory failed to document in the worksheet record the 1:2 serial dilution factor and the signature of the personnel who perform the test. The findings include: 1. Review on June 14, 2022 at 12:38pm, of the laboratory CRP modified procedure instructions showed that the laboratory must perform a 1:2 and 1:4 serial dilution to all samples how initially had a negative CRP result. 2. The testing records showed that the laboratory did not document the 1:2 serial dilution result from January 1, 2020 to June 13, 2022. The laboratory documents the initial CRP result and the 1:4 dilution. 2. The testing records showed that the laboratory did not include the signature of the personnel who perform the test of the patients specimen in the following testing records ASI CRP slide test in the following days: 1/11/2022, 1/12/2022, 2/28/2022, 6/7/2022. 3. The laboratory technical supervisor confirmed on June 14, 2022 at 12:42 pm, that the laboratory did not include the CRP 1:2 serial dilution when 1,914 out of 3,150 patient specimen were manually diluted, tested and reported. Neither the signature of the personnel who perform the test in the following days: 1/11/2022, 1/12/2022, 2/28/2022, 6/7/2022 was not included in the CRP testing records.
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 General Immunology quality control records review (2020-2022) and interview with the laboratory technical supervisor on June 14, 2022 at 12:45 pm, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements for general immunology. The finding includes: 1. The laboratory director failed to ensure compliance with the general immunology requirements. Refer to D6079.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are

	properly performed. This STANDARD is not met as evidenced by: Based on ASI C-Reactive Protein (CRP) slide test manufacturer's instructions, written procedure manual, testing records and laboratory technical supervisor interview on June 14, 2022 at 1:23 pm, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the facility have the necessary space for conducting all phases of the testing process. Refer D 3001 (facility did not have enough space for all testing phases).
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on C-reactive protein (CRP) test quality control records (year 2020 to 2022) review, manufacturer's instructions, procedure manual review and interview with the laboratory technical supervisor, on June 14, 2022 at 12:15 pm, it was determined that the laboratory director failed to establish the acceptable analytical performance for the ASI CRP slide test method. Refer to D 5014 (in the specialty of general immunology the laboratory did not meet the requirements).
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on quality control records review and laboratory technical supervisor interview on June 14, 2022 at 1:30pm, it was determined that the laboratory technical supervisor, failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control program. Refer to D6117 (The technical supervisor did not establish a quality control program appropiate for the C-Reactive Protein (CRP) testing performed).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by:

	Based on review of C-Reactive Protein (CRP) procedures manual, quality control records review, manufacturer's instructions and technical supervisor interview on June 14, 2022 at 12:15pm, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems. Refer to D 5014 (in the specialty of general immunology the laboratory did not meet the requirements).