Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0863294	03/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Villa Blanca	Lote 19 Blq A Calle Acuamarina Villa Blanca, Caguas, 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
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 for the susceptibility tests (years 2016 and 2017), bacteriology testing records (years 2016 and 2017) and general supervisor interview on March 27, 2018 at 9:00 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology for the antimicrobial susceptibility tests . The finding includes: 1. The laboratory did not check each day of testing (with the appropriate control organisms) the antimicrobial susceptibility tests when it processed 413 out of 413 patients specimens by the Vitek II system from January 1, 2016 to March 27, 2018. Refer to D 5507.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on general laboratory systems quality assessment written procedures and

	general supervisor interview on March 27, 2018 at 11:00 AM, it was determine that the laboratory failed to establish a protocol to evaluate the competence of the technical supervisor and the general supervisor since March 27, 2016. The findings include: 1. The general laboratory systems quality assessment written procedures showed that the laboratory did not establish a protocol to evaluate the competence of the technical supervisor and the general supervisor since March 27, 2016. 2. The personnel records showed that the laboratory did not perform the competence evaluation of the technical supervisor nor the general supervisor since March 27, 2016. The laboratory evaluated those personnel as testing personnel. 3. The general supervisor confirmed on March 27, 2018 at 11:05 AM, that the laboratory did not have protocol to evaluate the competence evaluation of the technical supervisor nor the general supervisor since March 27, 2016.
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 procedures manual, antinuclear antibody (ANA) testing records(2017, 2018) and technical supervisor interview on March 27, 2018 10:35 AM, it was determined that the laboratory failed to follow written procedures for the step-by-step performance of the ANA quantitative procedure when 10 out of 10 patients specimens were tested for ANA quantitative from January 27, 2017 to January 27, 2018. The findings include: 1. The procedures manual establish the step-by-step performance (reqiuere dilutions) for the ANA quantitative tests. 2. The ANA testing records showed that the laboratory did not follow the step-by-step performance of the ANA quantitative tests from January 27, 2017 to January 27, 2018. The laboratory did not documented the results of all reqiuere patient specimen dilutions. Instead, the laboratory documented the result of the final positive dilution. Also, the laboratory did not document the buffer solution (PBS) nor the negative control results of the positive quantitative control material smear. 2. The laboratory reported 10 out of 10 patients specimens were tested for ANA quantitative from January 27, 2017 to January 27, 2018: #345169, #345782, #359362, #358989, #360808, #363036, #362788, #362788, #362509 and #369322. 3. The technical supervisor confirmed on March 27, 2018 10: 40 AM, that the laboratory for the ANA quantitative tests, documented the result of

	the final positive dilution and did not document the PBS nor the negative control results of the positive control material smear.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of Advia 120 annual calibration records (2017), completed cell count (CBC) annual volume records (2017) and technical supervisor interview on March 27, 2018 at 10:50 AM, it was determined that the laboratory failed to perform the calibration procedures of the Advia 120 system during year 2017. The findings include: 1. The laboratory processed the patients CBC specimens by the Advia 120 system. 2. The calibration records (2017) of the Advia 120 system was not available in the laboratory. 3. The technical supervisor stated on March 27, 2018 at 10:50 AM, that the laboratory did not perform the Advia 120 system calibration during the year 2017. 4. The annual CBC volume records (2017) showed that the laboratory processed 11,565 CBC patients specimens during year 2017.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on bacteriology quality control records for the susceptibility tests (years 2016 and 2017), bacteriology testing records (years 2016 and 2017) and general supervisor interview on March 27, 2018 at 9:00 AM, it was determined that the laboratory failed to check each day of testing (with the appropriate control organisms) the antimicrobial susceptibility tests when it processed 413 out of 413 patients specimens by the Vitek II system from January 1, 2016 to March 27, 2018. The findings include: 1. The laboratory performed antimicrobial susceptibility test by the Vitek II system since January 1, 2016. 2. The bacteriology quality control records for the susceptibility tests showed, that the laboratory did not to check each day of testing (

	with the appropriate control organisms) the antimicrobial susceptibility tests when it processed patients specimens by the Vitek II system from January 1, 2016 to March 27, 2018. The laboratory checked weekly the antimicrobial susceptibility tests. 3. The general supervisor confirmed on March 27, 2018 at 9:10 AM, that the laboratory did not to check each day of testing the antimicrobial susceptibility tests. She stated that the laboratory checked weekly the Vitek II antimicrobial susceptibility tests. 4. The bacteriology testing records showed that the laboratory processed and reported the total of 413 patients specimens for the Vitek II antimicrobial susceptibility tests from January 1, 2016 to March 27, 2018: Year patients specimens/ patients specimens/ (susceptibility tests (susceptibility tests gram positive organism) (gram negative organism) 2016 59 188 2017 30 136
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on white blood cells (WBC) differential results comparison records (2016,2017, 2018), WBC differential patients results records (2016, 2017) and general supervisor interview on March 27, 2018 at 10:05 AM, it was determined that the laboratory failed to evaluates twice a year the relationship of the WBC differential results between the manual method and the Advia 120 system from January 2016 to March 27, 2018. The findings include: 1. The laboratory performed the WBC differential results by two method: manual examination and by the the Advia 120 system . 2. The WBC differential results comparison records showed that the laboratory did not evaluated twice a year the relationship of the WBC differential results between the manual method and the Advia 120 system from January 2016 to March 27, 2018. The laboratory performed the WBC differential results comparison on August 15, 2016 and on April 5, 2017. 3. The general supervisors confirmed on March 27, 2018 at 10:05 AM, that the laboratory did not evaluated twice a year the relationship of the WBC differential results between the manual method and the Advia 120 system from January 2016 to March 27, 2018. 4. The WBC differential patients results records showed that 3 out of 3 patients specimens reported with the WBC manual examination differential results and with the Advia 120 WBC differential results from January 2016 to March 27, 2018: #268, #6501001 and #2354.
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 for the susceptibility tests (years 2016 and 2017), bacteriology testing records (years 2016 and 2017) , procedures manual,

	ANA testing records(2017, 2018) , lack of Advia 120 annual calibration records (2017), CBC annual volume records (2017), WBC differential results comparison records (2016,2017, 2018), WBC differential patients results records (2016, 2017), general laboratory systems quality assessment written procedures, technical supervisor and general supervisor interview on March 27, 2018 at 11:05 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The findings include: 1. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093. 2. The laboratory director did not comply with the general laboratory system quality assessment requirements. Refer to 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 bacteriology quality control records for the susceptibility tests (years 2016 and 2017), bacteriology testing records (years 2016 and 2017) , procedures manual, ANA testing records(2017, 2018) , lack of Advia 120 annual calibration records (2017), CBC annual volume records (2017), WBC differential results comparison records (2016,2017, 2018), WBC differential patients results records (2016, 2017), technical supervisor and general supervisor interview on March 27, 2018 at 11:05 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements of Bacteriology for the antimicrobial susceptibility tests. Refer to D 5002. 2. The laboratory director failed to ensure compliance with the analytic system requirements of general immunology for the step-by-step performance of the ANA quantitative tests procedure. Refer to D 5403. 3. The laboratory director failed to ensure compliance with the analytic requirements of hematology for the Advia 120 system calibration procedures and for the for WBC differential comparison results. Refer to D 5437. Refer to D 5775.
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 general laboratory systems quality assessment written procedures and general supervisor interview on March 27, 2018 at 11:00 AM, it was determined that laboratory director failed to ensure compliance with the general laboratory system quality assessment requirements. The finding includes: 1. The laboratory director did not establish a mechanism to evaluate the competence of the technical supervisor nor the general supervisor since March 27, 2016. Refer to D 5293.

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 bacteriology quality control records for the susceptibility tests (years 2016 and 2017), bacteriology testing records (years 2016 and 2017) , procedures manual, ANA testing records(2017, 2018) , lack of Advia 120 annual calibration records (2017), CBC annual volume records (2017), WBC differential results comparison records (2016,2017, 2018), WBC differential patients results records (2016, 2017), technical supervisor and general supervisor interview on March 27, 2018 at 11:05 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems. Refer to D 5403, D 5437, D 5507 and D 5775.
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 for the susceptibility tests (years 2016 and 2017), bacteriology testing records (years 2016 and 2017) , procedures manual, ANA testing records(2017, 2018) , lack of Advia 120 annual calibration records (2017), CBC annual volume records (2017), WBC differential results comparison records (2016,2017, 2018), WBC differential patients results records (2016, 2017), technical supervisor and general supervisor interview on March 27, 2018 at 11:05 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results in the following laboratory areas: bacteriology, general immunology and hematology. Refer to D 5403, D 5437, D 5507 and D 5775
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 bacteriology quality control records for the susceptibility tests (years 2016 and 2017), bacteriology testing records (years 2016 and 2017) , procedures manual, ANA testing records(2017, 2018) , lack of Advia 120 annual calibration records (2017), CBC annual volume records (2017), WBC differential results comparison records (2016,2017, 2018), WBC differential patients results records (2016, 2017),

	technical supervisor and general supervisor interview on March 27, 2018 at 11:05 AM, it was determined that testing personnel failed to follow quality control procedures for bacteriology, general immunology and hematology. Refer to D 5403, D 5437, D 5507 and D5775.