Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	40D0666367	12/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Perea Clinical Laboratory	Calle Dr Basora # 15, Mayaguez, 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
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 and interview with the technical supervisor and blood bank testing personnel at 9:30 AM on December 17, 2019, it was determined that the laboratory did not have enough work space in the blood bank area necessary for conducting all phases of the following testing process: ABO group and Rh, antibody detection (transfusion), antibody detection (non transfusion), compatibility testing, cold agglutinin, syphilis serology, Influenza A/B, rheumatoid arthritis (RA) and Infectious mononucleosis (MONO) tests since January 1, 2018. The findings include: 1. At 9:30 AM on December 17, 2019, it is observed that the blood bank area includes two cabinets and had a working area approximately of of 2.5' (width) by 7.0' (length) between the two cabinets. Also, the two cabinets tops were strongly crowded with procedures manuals, centrifuges, rotator and papers without enough work space for conducting all phases of the following testing process: ABO group and Rh, antibody detection (transfusion), antibody detection (non transfusion), compatibility testing, cold agglutinin, syphilis serology, Influenza A/B, RA and MONO tests since January 1, 2018. 2. The technical supervisor and blood bank testing personnel stated at 9:30 AM on December 17, 2019, that they were aware of the space limitations.
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 cold agglutinin and syphilis serology quantitative tests procedure manual, cold agglutinin and syphilis serology quantitative tests testing records review (year 2019) and interview with the blood bank testing personnel at 10:10 AM on December 17, 2019, it was determined that the laboratory failed to follow written procedures for the step-by-step performance of those tests when 23 patients specimens were processed for cold agglutinin test and 14 patients specimens were processed for syphilis serology quantitative test from January 1, 2019 to December 17, 2019. The findings include: 1. The cold agglutinin test procedures manual instructed the laboratory to perform a serial dilution of the patient serum from 1:1 dils to 1:128 dils. 2. The syphilis serology quantitative test procedures manual instructed the laboratory to perform a serial dilution of the patient serum from 1:1 dils to 1: 256. 3. At 10:10 AM on December 17, 2019, the cold agglutinin and syphilis serology quantitative tests testing records showed that the laboratory did not document the step-by-step performance of those methods from January 1, 2019 to December 17, 2019. The laboratory documented the highest patient serum dilution with a reactive results. 4. The blood bank testing personnel confirmed at 10:10 AM on December 17, 2019, that the laboratory did not document the step-by-step performance of the cold agglutinin and syphilis serology quantitative tests, she stated that the laboratory performed the required dilutions but the laboratory only documented the highest patient serum dilution with a reactive results. 5. . The laboratory processed and reported 23 patients specimens for cold agglutinin test and 14 patients specimens for syphilis serology quantitative test from January 1, 2019 to December 17, 2019.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 1. Based on Clinitek Novus manufacturer's instructions, Clinitek Novus system preventive maintenance records (year 2019) review and interview with the technical superviosr at 12:05 PM on December 17, 2019, it was determined that the laboratory failed to follow preventive maintenance instructions for the Novus system when 12,

	430 urine patients were processed and reported for urinalysis from April 1, 2019 to December 17, 2019. The findings include: a. The Clinitek Novus manufacturer instructed the laboratory to perform a weekly preventive maintenance (clean of the Rack pushers). b. At 12:05 PM on December 17, 2019, the Clinitek Novus system preventive maintenance records showed that the laboratory did not performed the require weekly clean from April 1, 2019 to December 17, 2019: 1. April 2019: not performed in 1 out of 4 weeks. 2. May 2019: not performed in 1 out of 4 weeks. 3. June 2019: not performed in 1 out of 4 weeks. 4. July 2019: not performed in 2 out of 4 weeks. 5. August 2019: not performed in 1 out of 4 weeks. 6. September 2019: not performed in 1 out of 4 weeks. 7. October 2019: not performed in 4 out of 4 weeks. 8. November 2019: not performed in 4 out of 4 weeks. c. The technical superviosr confirmed at 12:05 PM on December 17, 2019, that the laboratory did not evidence that the preventive maintenance was performed at weekly bases. d. The laboratory processed and reported 12, 430 urine patients specimens by the Novus system from April 1, 2019 to December 17, 2019. 2. Based on lack of preventive maintenance records for the Sedimat 15 plus system and interview with the technical superviosr at 12:23 PM on December 17, 2019, it was determined that the laboratory failed to perform the preventive maintenance of the Sedimat 15 plus system when 3,820 patients specimens were processed fro sedimentation rate tests from January 7, 2019 to December 17, 2019. The findings include: a. The laboratory did not perform nor document preventive maintenance records for the Sedimat 15 plus system from January 7, 2019 to December 17, 2019. b. The technical superviosr at 12:23 PM on December 17, 2019 confirmed that the laboratory did not document nor maintain the preventive maintenance records for the Sedimat 15 plus system. c. The laboratory processed 3,820 patients specimens for sedimentation rate tests by the Sedimat 15 plus system from January 7, 2019 to December 17, 2019.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of sedimentation rate test (ESR) control materials statistical parameters since January 7, 2019, ESR testing records review and interview with the technical superviosr at 12:23 PM on December 17, 2019, it was determined that the laboratory did not evaluate nor define the statistical values of all the lot numbers of the commercial ESR control material used by the Sedimat 15 plus system when 3,820 patients specimens were processed for ESR test from January 7, 2019 to December 17, 2019. The findings include: 1. The laboratory did not define any statistical data (Levy-Jennings, control value mean and limits) of each ESR control materials used

	since January 7, 2019. 2. The technical superviosr confirmed at 12:23 PM on December 17, 2019, that the laboratory did not define any statistical data (Levy-Jennings, control value mean and limits) of each ESR control materials used since January 7, 2019. 3. The laboratory processed 3,820 patients specimens for ESR test by the Sedimat 15 plus system from January 7, 2019 to December 17, 2019.
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 observation and interview with the technical supervisor and blood bank testing personnel at 9:30 AM on December 17, 2019, it was determined that the laboratory director failed to ensure that the blood bank area have enough work space necessary for conducting all phases of the following testing process: ABO group and Rh, antibody detection (transfusion), antibody detection (non transfusion), compatibility testing, cold agglutinin, syphilis serology, Influenza A/B, rheumatoid arthritis (RA) and Infectious mononucleosis (MONO) tests since January 1, 2018. Refer to D 3001.
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 cold agglutinin and syphilis serology quantitative tests procedure manual, cold agglutinin and syphilis serology quantitative tests testing records(year 2019), Clinitek Novus manufacturer's instructions, Clinitek Novus system preventive maintenance records (year 2019) review, lack of preventive maintenance records for the Sedimat 15 plus system, lack of sedimentation rate test (ESR) control materials statistical parameters, interview with the technical superviosr and blood bank testing personnel at 12:23 PM on December 17, 2019, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D 5403 (The laboratory did not follow written procedures for the step-by-step performance of those tests when 23 patients specimens were processed for cold agglutinin test and 14 patients specimens were processed for syphilis serology quantitative test from January 1, 2019 to December 17, 2019). Refer to D 5429 (1) (The laboratory did not follow preventive maintenance instructions for the Novus system when 12, 430 urine patients

	were processed and reported for urinalysis from April 1, 2019 to December 17, 2019). Refer to D 5429 (2) (The laboratory failed to perform the preventive maintenance of the Sedimat 15 plus system when 3,820 patients specimens were processed fro sedimentation rate tests from January 7, 2019 to December 17, 2019). Refer to D 5469 (The laboratory did not evaluate nor define the statistical values of all the lot numbers of the commercial ESR control material used by the Sedimat 15 plus system when 3,820 patients specimens were processed for ESR test from January 7, 2019 to December 17, 2019).
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 cold agglutinin and syphilis serology quantitative tests procedure manual, cold agglutinin and syphilis serology quantitative tests testing records(year 2019), Clinitek Novus manufacturer's instructions, Clinitek Novus system preventive maintenance records (year 2019) review, lack of preventive maintenance records for the Sedimat 15 plus system, lack of sedimentation rate test (ESR) control materials statistical parameters, interview with the technical superviosr and blood bank testing personnel at 12:23 PM on December 17, 2019, it was determined that the technical superviosr failed to establish and maintain quality control procedures. Refer to D 5403 (The laboratory did not follow written procedures for the step-by-step performance of those tests when 23 patients specimens were processed for cold agglutinin test and 14 patients specimens were processed for syphilis serology quantitative test from January 1, 2019 to December 17, 2019). Refer to D 5429 (1) (The laboratory did not follow preventive maintenance instructions for the Novus system when 12, 430 urine patients were processed and reported for urinalysis from April 1, 2019 to December 17, 2019). Refer to D 5429 (2) (The laboratory failed to perform the preventive maintenance of the Sedimat 15 plus system when 3,820 patients specimens were processed fro sedimentation rate tests from January 7, 2019 to December 17, 2019). Refer to D 5469 (The laboratory did not evaluate nor define the statistical values of all the lot numbers of the commercial ESR control material used by the Sedimat 15 plus system when 3,820 patients specimens were processed for ESR test from January 7, 2019 to December 17, 2019).
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 cold agglutinin and syphilis serology quantitative tests procedure manual, cold agglutinin and syphilis serology quantitative tests testing records(year 2019),

	Clinitek Novus manufacturer's instructions, Clinitek Novus system preventive maintenance records (year 2019) review, lack of preventive maintenance records for the Sedimat 15 plus system, lack of sedimentation rate test (ESR) control materials statistical parameters, interview with the technical superviosr and blood bank testing personnel at 12:23 PM on December 17, 2019, it was determined that the testing personnel failed to follow quality control procedures. Refer to D 5403 (The laboratory did not follow written procedures for the step-by-step performance of those tests when 23 patients specimens were processed for cold agglutinin test and 14 patients specimens were processed for syphilis serology quantitative test from January 1, 2019 to December 17, 2019). Refer to D 5429 (1) (The laboratory did not follow preventive maintenance instructions for the Novus system when 12, 430 urine patients were processed and reported for urinalysis from April 1, 2019 to December 17, 2019). Refer to D 5429 (2) (The laboratory failed to perform the preventive maintenance of the Sedimat 15 plus system when 3,820 patients specimens were processed fro sedimentation rate tests from January 7, 2019 to December 17, 2019). Refer to D 5469 (The laboratory did not evaluate nor define the statistical values of all the lot numbers of the commercial ESR control material used by the Sedimat 15 plus system when 3,820 patients specimens were processed for ESR test from January 7, 2019 to December 17, 2019).