Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658006	05/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bayamon Medical Center	Carr #2 Km 11 Hm 7, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on routine chemistry quality control records review and interview with the laboratory director and laboratory general supervisor on May 17, 2018 at 2:0 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry tests. The findings include: 1. The laboratory failed to follow written instructions to perform the quality control evaluation for Dimension system. Refer to D5403. 2. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (electrolytes) tests processed by the Dimension RxL- Max system. Refer to D5439. 3. The laboratory failed to take and document remedial actions when the normal and abnormal control do not meet the laboratory's criteria for acceptability. Refer to D5783.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of body fluid quality control and patient test records, it was found

	that the laboratory failed to ensure compliance with the analytic system requirements for hematology. The finding includes: a. The laboratory used body fluids control material beyond the stability date nor include control material . Refer to D5479 and D5543
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 routine chemistry procedure manual and laboratory general supervisor interview on May 17, 2018 at 11:30 A.M., it was determined that the laboratory failed to follow written instructions to perform the quality control evaluation for Dimension system. The findings include: 1. The laboratory performed routine chemistry test by Dimension RxL-Max system. 2. The laboratory used two level control material (normal and abnormal) to evaluate the routine chemistry performance. 3. The routine chemistry quality control written procedure for Dimension system stated that the laboratory must be evaluated monthly the quality control data using the previous month data to calculate the next data. 4. The laboratory must used the statistical data of the previous month to evaluate the next month quality control results. 5. The written instructions stated that the laboratory must print the graphs for all analytes monthly. 6. The laboratory did not evaluate not print the routine chemistry quality control graphs from September 27, 2018 to December 21, 2017 (lot: 45781 and 45783) and from January 1, 2018 to May 2018 (lot: 1221UN and 909UE) . 7. The routine chemistry supervisor stated on May 17, 2018 that the laboratory did not follow the written procedure to evaluate the routine chemistry quality control data since September 27, 2017. 8. The laboratory processed and reported 225,098 routine chemistry patient samples from September 2017 to April 2018.
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 verification records review (year 2016 to 2018) and interview with the routine chemistry supervisor on May 17, 2018 at 1:00 P. M., it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (sodium, potassium and chloride) tests processed by the Dimension RxL- Max system. The findings include: 1. The laboratory used the Dimension RxL- Max system to perform routine chemistry tests. 2. Review of the calibration verification records showed that the procedures were performed (for year 2017) on March 2017 and December 2017. 3. The routine chemistry supervisor confirmed on May 17, 2018 that the laboratory did not perform the calibration verification procedures for electrolytes tests in 2017 , at least every 6 months.
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 review of manufacturer's quality control material insert, patient records, quality control records review (year 2016 to 2018) and interview with the testing personnel on May 17, 2016, it was found that the laboratory did not follow the manufacturer's instructions regarding the stability of the body fluids quality control material. The findings includes: a. On May 17, 2018 at 11:40 AM the hematology area testing personnel showed the body fluid records (quality control and patient test results). The testing personnel stated that the laboratory performed body fluids cell count using the hemocytometer. b. Review of the manufacturer's quality control insert showed that the control vials were stable up to 30 days after opening. c. Review of the laboratory body fluid quality control records showed that the laboratory documented the expiration date of the control in the upper right corner of each page. d. The quality control and patient records showed that the laboratory used control material beyond

	the stability date when the following patient samples were tested on: Date Control Patient of testing expiration date sample 8/22/2017 8/20/2017 4443367 9/3/2017 8/20 /2017 4452630 3/12/2018 3/10/2018 4576855 3/28/2018 3/10/2018 4587378 4/29 /2018 4/11/2018 4606996 e. The laboratory used quality control material beyond it's stability date in 5 out of 86 days.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on body fluids quality control, patient test records (years 2016 to 2018) and interview with the hematology testing personnel on May 17, 2018 at 11:40 AM, it was found that the laboratory did not included a control material each eight hours of testing. The findings include: a. The hematology testing personnel stated on May 17, 2018 at 11:40 AM, that the laboratory performed body fluid cell count using an hemocytometer. He also stated that two levels of control materials must be included. b. Review of the body fluids quality control and patient test records showed that the laboratory did not include any control material when they performed body fluid cell counts on: Date Patient sample 11/18/2016 4229113 2/10/2017 4299452 11/2/2017 4486741 11/8/2017 4491118 3/14/2018 4578107 3/27/2018 4586633 c. The hematology testing personnel stated that the control material was not included during those days.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on routine chemistry quality control records review and laboratory routine chemistry supervisor interview on May 17, 2018 at 11:30 A.M., it was determined that the laboratory failed to take and document remedial actions when the normal and abnormal control did not meet the laboratory's criteria for acceptability. The findings include: 1. The laboratory performed routine chemistry test by Dimension RxL-Max system. 2. The laboratory used two level control material (normal and abnormal) to evaluate the routine chemistry performance. 3. From September 27, 2018 to December 21, 2017 (lot: 45781 and 45783) and from January 5,2018 to May 18, 2018 (lot: 1221 and 909), the quality control showed that the laboratory did not evaluate the quality control statistics data. 4. The quality control graphs showed that the routine chemistry tests controls values had trends (below or above the established

	range) for all analytes processed and the laboratory did not take nor document remedial actions in those months. 5. The laboratory processed and reported 225,098 routine chemistry patient samples from September 2017 to April 2018.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) 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 routine chemistry quality control records review and interview with the laboratory director and laboratory general supervisor on May 17, 2018 at 2:0 P.M., it was determined that the technical consultant failed to ensure compliance with the analytic system requirements for routine chemistry tests. The findings include: 1. The laboratory failed to follow written instructions to perform the quality control evaluation for Dimension system. Refer to D5403. 2. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (sodium, potassium and chloride) tests processed by the Dimension RxL-Max system. Refer to D5439. 3. The laboratory failed to take and document remedial actions when the normal and abnormal control do not meet the laboratory's criteria for acceptability. Refer to D5783.
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 hematology (body fluids) and general chemistry quality control records review on May 17, 2018, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer D 6093 and 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: 1. Based on body fluids control records review and interview with the laboratory testing personnel on May 17, 2018 at 11:40 AM, it was determined that the laboratory director did not make sure that control material were not used after it's stability date

	not assure that control materials were included. Refer to D 5024. 2. Based on routine chemistry quality control records review and interview with the laboratory director and laboratory general supervisor on May 17, 2018 at 2:00 P.M., it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for routine chemistry tests. Refer to D5016.
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 review of Quality Assessment (QA) records and interview with the laboratory supervisors (# 1 and #2) on May 17, 2018 at 1:45 PM, it was determined that the laboratory director did not ensure the establishment of a QA program for year 2017 and 2018. The finding include: a. The only QA evaluation performed by the laboratory for the last trimester of 2017 and the first of 2018 was evaluations of the facility turn around time. b. The general supervisors stated that they did not have the QA evaluations performed by the former laboratory director.
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: 1. Based on body fluids quality control records and interview with the testing personnel on May 17, 2018 at 11:40 AM, it was determined that testing personnel failed follow quality control requirements for body fluids tests. The finding includes: a. The testing personnel used control material beyond the stability date and did not include control material when patient samples were tested. Refer to D5479 and D5543. 2. Based on routine chemistry quality control records and interview with the testing personnel on May 17, 2018 at 11:30 AM, it was determined that testing personnel failed follow quality control requirements for routine chemistry tests. The finding includes: a. The testing personnel failed to follow written instructions to perform the quality control evaluation for Dimension system and failed to take and document remedial actions when the normal and abnormal control did not meet the laboratory's criteria for acceptability. Refer to D5403 and D5783.