Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0669892	05/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bayamon Medical Center	Carr Num 2, Km11, 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
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records review and interview with the Blood Bank technical supervisor and testing personnel # 1 on May 17, 2018 at 10:10 AM, it was determined that the blood bank facility failed to ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. The findings include: 1. On May 17, 2018 at 1:40 PM, the 4 blood unit returned sheets records showed that 4 out of 4 blood units were issued from the blood bank on January 9, 2018 and returned on January 12, 2016; the 4 blood units were stored in the "Cardio Refrigerator" (out side the blood bank). All blood units were returned to the general blood inventory, reissued and transfused: a. Unit W236417078410 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 16, 2018 (patient #1). b. Unit W236517358481 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 15, 2018 (patient #2). c. Unit W236517356800 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 15, 2018 (patient #3). d. Unit W236517358364 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 16, 2018 (patient #4). 2. The SOP for the blood unit returned did not include the instructions to store out side the blood bank the

	blood unit returned. 3. The Blood Bank technical supervisor confirmed on May 17, 2018 at 1:40 PM, that those blood unit were issued from the blood bank on January 9, 2018 and returned on January 12, 2016. He stated that the four blood units were returned to the general blood inventory, reissued and transfused. He stated that those blood units were stored in the "Cardio Refrigerator" (out side the blood bank). 4. On May 17, 2018 at 1:40 PM, the blood bank did not have records for the Temperature monitoring of the "Cardio refrigerator" from January 1, 2018 to May 17, 2018. At 3: 00 PM, the Blood Bank technical supervisor brought the temperature chart of the "Cardio refrigerator".
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records, direct observation, Refrigerator # 1 temperature chart records review and blood bank technical supervisor interview on May 17, 2018 at 1:40 PM, it was determined that the blood bank failed to meet the quality control requirements for the subspecialty of Immunohematology. Refer to D 5403 ((The blood bank failed to have and follow written procedures describing how the blood bank verifies the internal temperature of the returned blood units). Refer to D 5405 (The blood bank failed to follow written procedures to verify the temperature of all blood units that were issued from the blood bank but not transfused in order to determine if those products can be returned to the general blood inventory to be later reissued safely or discarded). Refer to D 5555 (The blood bank failed to assure that the blood units were stored under appropriate conditions from January 6, 2017 to May 17, 2018).
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 Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records review and interview with the Blood Bank technical supervisor and testing personnel # 1 on May 17, 2018 at 10:10 AM, it was determined that the blood bank failed to have an follow written procedures that describe, step-by-step, how the blood bank verifies the temperature of previously release units that were returned to the bank without being transfused. The findings include: 1. The procedure manual did not include specific steps showing how the testing personnel will verify the temperature on returned blood units. 2. The blood unit returned sheets records showed that blood bank documented a temperature of 5 C in 7 out 7 blood units returned, all the 7 blood units were reissued and transfused: a. Unit W236417078410 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 16, 2018 (patient #1). b. Unit W236517358481 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 15, 2018 (patient #2). c. Unit W236517356800 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 15, 2018 (patient #3). d. Unit W236517358364 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 16, 2018 (patient #4). e. Unit W236518369641 released from the transfusion service on March 20, 2018 at 1:27 AM. Returned on March 20, 2018 at 1:40 AM. Temperature recorded 5C. Accepted to be used. Transfused on March 23, 2018 (patient #5). f. Unit W236518312839 released from the transfusion service on April 5, 2018 at 2:20 AM. Returned on April 5, 2018 at 2:40 AM. Temperature recorded 5C. Accepted to be used. Transfused on April 7, 2018 (patient #6). g. Unit W236318073290 released from the transfusion service on April 1, 2018 at 9:28 PM. Returned on April 1, 2018 at 9:44 PM. Temperature recorded 5C. Accepted to be used. Transfused on April 2, 2018 (patient #7). 3. On May 17, 2018 at 10:10 AM, during interview the testing personnel # 1 stated that the blood bank did not have a blood unit temperature monitoring system since the last two years, in order to verify the returned blood units ' temperatures. 4. The Blood Bank technical supervisor confirmed on May 17, 2018 at 10:10 AM that the blood bank did not have a blood unit temperature monitoring system since the last two years, in order to verify the returned blood units ' temperatures. He stated that the temperature of the blood unit returned was calculated but he could specify how the blood bank calculates the temperature of the blood units returned.
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 Immunohematology procedures manual, quality control records, blood unit return sheets records, compatibility testing records review and interview with the

	Blood Bank technical supervisor and testing personnel # 1 on May 17, 2018 at 10:10 AM, it was determined that the blood bank failed to follow written procedures to verify the temperature of all blood units that were issued from the blood bank but not transfused in order to determine if those products can be returned to the general blood inventory to be later reissued safely or discarded. The findings include: 1. The procedures manual established to verify, the temperature of all blood units that were issued from the blood bank but not transfused in order to determine if those products can be returned to the general blood inventory to be later reissued safely. The returned blood unit temperature should not exceed the the temperature range from 1 to 10 C and the returned blood unit should not exceed the 30 minutes returned to the general blood inventory to be later reissued safely. 2. Review of the blood unit return sheets to the transfusion services included the following instructions: a. "The returned unit must meet the following requirements": 1. Received from within 30 minutes of having left the transfusion service. 2. Close system. 2. Temperature within 1 to 10 C. "If it does not meet these requirements, blood will be discarded. If you meet these requirements, the blood will be quarantined". 3. Four out of four blood unit return sheets were review on May 17, 2018 at 1:45 PM showing the following: a. Unit W236417078410 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 16, 2018 (patient #1). b. Unit W236517358481 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 15, 2018 (patient #2). c. Unit W236517356800 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 15, 2018 (patient #3). d. Unit W236517358364 released from the transfusion service on January 9, 2018. Returned on January 12, 2018. Temperature recorded 5C. Accepted to be used. Transfused on January 16, 2018 (patient #4). 4. The Blood Bank technical supervisor confirmed on May 17, 2018 at 1:45 PM that those unit were accepted and transfused. 5. The blood bank failed to have an follow written procedures that describe, step-by-step, how the blood bank verifies the temperature of previously release units that were returned to the bank without being transfused. Refer to D 5403.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on direct observation, Refrigerator # 1 temperature chart records review and blood bank technical supervisor interview on May 17, 2018 at 11:05 AM, it was determined that the blood bank failed to assure that the blood units were stored under appropriate conditions from January 6, 2017 to May 17, 2018. The findings included: 1. It was observed on May 17, 2018 at 11:05 AM, that the right and the left door of the Refrigerator # 1 did not close properly. When the testing personnel opens and closes the right door of the Refrigerator # 1, the left door opens automatically and must be closed it carefully so that the right door does not open again. 2. The Refrigerator # 1 temperature chart records showed that the doors of the Refrigerator #

	1 were found open in the following dates from January 6, 2017 to May 17, 2018: January 6, 2017, January 8, 2017, May 8, 2017, October 26, 2017, November 3, 2017, November,6 2017, November 8, 2017, November 27, 2017, December 21, 2017, December 26, 2017, December 28, 2017, January 8, 2018, January 19, 2018, February 4, 2018, February 27, 2018, March 19, 2018, April 1, 2018, April 8, 2018, April 19,2018 and April 24, 2018. 3. The blood bank technical supervisor confirmed on May 17, 2018 at 11:05 AM, that the two doors of the Refrigerator # 1 did not close properly. He stated and documented in the temperature chart records that those days the blood units were not affected. 4. The blood bank did not taken remedial actions to fix the doors of the Refrigerator # 1. 5. From May 17, 2016 to May 17, 2017, the blood bank performed 7,373 out of 7,373 blood units transfusions.
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 Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records, direct observation, Refrigerator # 1 temperature chart records review and blood bank technical supervisor interview on May 17, 2018 at 1:40 PM, it was determined that the blood bank 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 blood bank director did not comply with the analytical systems requirements for the subspecialty of Immunohematology. Refer to D 6093. 2. The blood bank director did not ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product stored out side the Blood Bank. Refer to D 6079.
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 Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records review and interview with the Blood Bank technical supervisor and testing personnel # 1 on May 17, 2018 at 10:10 AM, it was determined that the blood bank director failed to ensure the storage conditions,

	including temperature, are appropriate to prevent deterioration of the blood or blood product stored out side the Blood Bank. Refer to D 3021.
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 Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records, direct observation, Refrigerator # 1 temperature chart records review and blood bank technical supervisor interview on May 17, 2018 at 1:40 PM, it was found that the blood bank director failed to ensure compliance with the analytic system requirements for the subspecialty of Immunohematology. The finding includes: 1. The blood bank director failed to ensure compliance with the analytic system requirements for the subspecialty of Immunohematology. Refer to D 5026.
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 Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records, direct observation, Refrigerator # 1 temperature chart records review and blood bank technical supervisor interview on May 17, 2018 at 1:40 PM, it was found that the blood bank technical supervisor failed to fulfill his responsibilities and duties to ensure compliance with the analytic system requirements for the subspecialty of Immunohematology. The findings include: 1. The blood bank technical supervisor did not qualify for the position. D 6109. 2. The blood bank technical supervisor failed to ensure compliance with the analytic system requirements for the subspecialty of Immunohematology. Refer to D 6117.
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on blood bank personnel records review and interview with the technical

	supervisor on May 17, 2018 at 1:30 AM, it was determined that the technical supervisor did not qualify for the position. The finding includes: 1. The blood bank technical supervisor did not qualify for the position. The technical supervisor is a medical technologist.
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 Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records, direct observation, Refrigerator # 1 temperature chart records review and blood bank technical supervisor interview on May 17, 2018 at 1:40 PM, it was found that the blood bank technical supervisor failed to ensure compliance with the analytic system requirements for the subspecialty of Immunohematology. The finding includes: 1. The blood bank technical supervisor failed to ensure compliance with the analytic system requirements for the subspecialty of Immunohematology. Refer to D 5026.
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 Immunohematology procedures manual, quality control records, blood unit returned records, compatibility testing records, direct observation, Refrigerator # 1 temperature chart records review and blood bank technical supervisor interview on May 17, 2018 at 1:40 PM, it was determined that the blood bank testing personnel failed to follow quality control procedures Refer to D 5403 ((The blood bank failed to have and follow a written procedures describing how the blood bank verifies the internal temperature of the returned blood units).