Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658315	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Episcopal San Lucas Metro	Carretera Estatal 844, Km 0, Hm 5 Bo Cupey Bajo, Rio Piedras, 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 observations, procedure manual, inmunohematology quality control records review in 2016-2018 and laboratory director interview at 1:00 PM on January 30, 2018, it determined that the laboratory failed to store blood products for transfusion under appropriate conditions that include an adequate temperature alarm system that will be regularly inspected. The findings include: 1. The laboratory use a Forma Scientific Blood Bank Refrigerator to storage a blood products for transfusion. 2. The laboratory transfusion services procedure manual in "procedimiento 020" establishes that the laboratory must be assure that the refrigerator alarm system is programmed so that action can be taken before the blood products for transfusion reaches unacceptable temperatures outside the specifications. 3. Review of records from January 2016 to January 2018, the laboratory did not document the verification and function of the alarm system for Forma Scientifc Blood Bank Refrigerator since January 2016. 4. On January 30, 2018 the Blood Bank Refrigerator had one PRBC unit (packed red blood cell #W236317068140) O negative. The PRBC units storage in Blood Bank Refrigerator was in 2016 three hundred thirty one (331), in 2017 one hundred fifty eight (158) and 2018 twenty three (23). 5. The laboratory director confirmed on January 30, 2018, that the laboratory failed to monitor the Blood Bank Refrigerator with a programmable alarm system but the laboratory documented the blood bank refrigerator temperature every four hours.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, special chemistry quality control records review in 2016-2018 and laboratory director interview at 11:45 AM on January 30, 2018, it was determined that the laboratory failed to assure that the laboratory's equipment (Kenmore -freezer) was within acceptable limits to store troponin controls. The findings include: 1. The laboratory performed troponin patient's sample test by Pathfast system. 2. The manufacturer's establishes that the troponin controls (Liquichek Cardiac Markers Plus Control I, II and III) must be stored at a temperature between -20C to -70C. 3. Preventive maintenance records were reviewed since 2016. 4. From January 2016 to January 2018, the laboratory use a Kenmore refrigerator to storage the special chemistry (Troponins) controls material and 196 of 366 days in 2016, 105 of 365 days in 2017, 31 of 31 days in 2018 the laboratory was documented temperatures from -17 C to -19C (out of range). 5. The laboratory processed and reported one thousand four hundred sixty eight (1,468) troponin patient's samples in 2016, one thousand five hundred seventy (1,570) in 2017 and one hundred forty two (142) in 2018. 6. The laboratory director confirmed on January 31, 2018 that the laboratory failed to assure the acceptable limits ranges for troponin material controls in this freezer.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review in 2016-2018 and laboratory director interview on January 30, 2018 at 11:45 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The finding includes: 1. The laboratory failed to assure that the laboratory's equipment (Kenmore -freezer) was within acceptable limits to store troponin controls. Refer to D5413.
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 special chemistry quality control records review in 2016-2018 and laboratory director interview at 11:45 AM on January 30, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5413.
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 Quality Assessment (QA) records review in 2016-2018 and laboratory director interview on January 30, 2018 at 11:45AM, it was determined that laboratory director failed to ensure compliance with quality assessment requirements. Refer to D5791.
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 quality control records review in 2016-2018 and laboratory director interview on January 30, 2018 at 11:45 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory failed to assure that the laboratory's equipment (Kenmore -freezer) was within acceptable limits to store troponin controls. Refer to D5413.