Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2121312	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Centro Comprensivo De Cancer	Carr Pr-18, Esq Carr Pr-21, San Juan, 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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on test requisition records results and laboratory director interview on October 30, 2018 at 2:00 PM, it was determined that the laboratory failed to ensure that tests requisition includes the date and the time of specimen collection from June 14, 2018 to July 5, 2018. The findings include: 1. The test requisition records showed that three out of three test requisitions did not include the time of collection: requisition of patients # 18-0030 for rheumatoid factor-RA test; requisition of patients # 18-0018 for glucose and CPK tests and requisition of patients # 18-0072 for urine culture test. 2. The test requisition records showed that one out of three test requisitions did not include the date of collection: requisition of patients # 18-0018 for glucose and CPK tests. 3. the laboratory director confirmed that those requisitions did not include the required information.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on blood culture specimen collection written protocol, bacteriology testing records and technical superviosr (bacteriology area) interview on October 30, 2018 at 1:10 PM, it was determined that the laboratory failed to establish and follow written protocol for the collection of blood culture patients specimen. The findings include: 1. The written protocol for the specimen collection of blood culture instructed the laboratory to collect every 15 minutes one out of three blood culture bottlers per patients.. 2. The written protocol did not include the specific time when the blood culture specimens should be receiving in the laboratory after collection. 3. The bacteriology testing records showed that the laboratory did not follow written procedures for the blood culture specimen collection of the patient # 4445 on October 19, 2018: a. The bottle number 1 was taken at 7:30 PM, the bottle number 2 was at 8: 19 PM and the bottler number 3 was taken at 8:25 PM. b. The bottle number 1 and bottle number 2 was received in the laboratory taken at 8:31 PM and the bottler number 3 was received in the laboratory taken at 9:19 PM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation records of Cobas 6000 system and laboratory director interview on October 30, 2018 at 9:00 AM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 341 out of 314 patient routine chemistry test results by Cobas 6000 system from June 1, 2018 to September 30, 2018. The findings include: 1. The laboratory validated the Cobas 6000 system on February 21, 2018 to perform the routine chemistry tests. 2. The laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 341 out of 314 patient routine chemistry test results by Cobas 6000 system from June 1, 2018 to September 30, 2018. 3. The laboratory director confirmed on October 30, 2018 at 9:00

	AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient routine chemistry test results by Cobas 6000 system.
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: Based on preventive maintenance records review and interview with the technical supervisor (bacteriology area) on October 30, 2018 at 1:10 PM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of the Vitek 2 system. The findings include: 1. The maintenance records of the Vitek 2 system showed that the laboratory did not perform the monthly preventive maintenance of this system in July 2018, August 2018 and September 2018. 2. The technical supervisor (bacteriology area) confirmed on October 30, 2018 at 1:10 PM, that the maintenance records showed no documentation for the monthly preventive maintenance in those month. She stated that the monthly preventive maintenance were performed but not documented in July 2018, August 2018 and September 2018. 3. The laboratory processed 4 patients specimens in the bacteriology area from June 1, 2018 to September 30, 2018.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on laboratory test reports records review and laboratory director interview on October 30, 2018 at 2:00 PM, it was determined that the laboratory failed to indicate the address of the laboratory location in the bacteriology and routine chemistry tests results reported from June 1, 2018 to September 30, 2018. The findings include: 1. The test reports records showed that the laboratory laboratory did not indicate the address of the laboratory location in 4 out 4 bacteriology tests results and 341 out of 341 routine chemistry tests results reported from June 1, 2018 to September 30, 2018. 2. The laboratory director confirmed on October 30, 2018 at 2:00 PM, that those tests result reports did not indicate the address of the laboratory location.
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 review of validation records of Cobas 6000 system and laboratory director interview on October 30, 2018 at 9:00 AM, it was determined that the technical consultant failed to ensure that the laboratory verified that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 341 out of 314 patient routine chemistry test results by Cobas 6000 system from June 1, 2018 to September 30, 2018. Refer to D 5421.
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 test requisition records results, blood culture specimen collection written protocol, bacteriology testing records, laboratory test reports records review, technical superviosr (bacteriology area) and laboratory director interview on October 30, 2018 at 2:00 PM, it was determined that the laboratory director failed to ensure that the tests requisition and tests reports include the require information for assuring compliance with the applicable regulations. Refer to D 5305 (The laboratory director interview on October 30, 2018 at 2:00 PM, it was determined that the laboratory failed to ensure that tests requisition includes the date and the time of specimen collection from June 14, 2018 to July 5, 2018). Refer to D 5311 (The laboratory failed to establish and follow written protocol for the collection of blood culture patients specimen). Refer to D 5805 (The laboratory failed to indicate the address of the laboratory location in the bacteriology and routine chemistry tests results reported from June 1, 2018 to September 30, 2018).
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 review of validation records of Cobas 6000 system, Vitek 2 system preventive maintenance records, technical supervisor (bacteriology area) and laboratory director interview on October 30, 2018 at 1:10 PM, it was determined that the laboratory director failed to ensure that the quality control programs are maintained to assure the quality of laboratory services provided. Refer to D 5421 (The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 341 out of 314 patient routine chemistry test results by Cobas 6000 system from June 1, 2018 to September 30, 2018). Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of the Vitek 2 system).
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 preventive maintenance records review and interview with the technical supervisor (bacteriology area) on October 30, 2018 at 1:10 PM, it was determined that the technical supervisor failed to ensure that the laboratory followed written instructions for the preventive maintenance of the Vitek 2 system. Refer to D 5429.
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: D5421 Based on review of validation records of Cobas 6000 system and laboratory director interview on October 30, 2018 at 9:00 AM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 341 out of 314 patient routine chemistry test results by Cobas 6000 system from June 1, 2018 to September 30, 2018. D5429 Based on preventive maintenance records review and interview with the technical supervisor (bacteriology area) on October 30, 2018 at 1: 10 PM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of the Vitek 2 system.