Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658243	(X3) Date Survey Completed 05/24/2019
Name of Provider or Supplier Cdt - San Juan Health Centre Clinic	**Street Address, City, State** 150 Ave De Diego, 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
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 Dimension EXL system manufacturer's instructions, Dimension Cuvette record temperature review (year 2019) and technical supervisor interview on May 24, 2019 at 11:40 AM, it was determined that the laboratory failed to follow the Dimension EXL manufacturer's instruction when 100 percent patients specimens were processed and reported for routine chemistry tests by the Dimension EXL system from January 2, 2019 to May 17, 2019. The findings include: 1. The laboratory processed the 100 percent of the routine chemistry tests by the Dimension EXL system. 2. The Dimension EXL system manufacturer establish the cuvette temperature range from 36.8 C to 37.2 C. 3. On May 24, 2019 at 11:40 AM, the Dimension EXL system temperatures records showed that the laboratory processed and reported the 100 percent of patients specimens out of the cuvette temperature range the following dates from January 2, 2019 to May 17, 2019: a. From January 2, 2019 to January 31, 2019: 20 out of 21 days at 36.7 C. b. From February 1, 2019 to February 28, 2019: 17 out of 19 days at 36.7 C. c. From March 1, 2019 to March 29, 2019: 18 out of 21 days at 36.7 C. d. From April 1, 2019 to April 30, 2019: 20 out of 20 days, 18 days at 36.7 C and 2 days at 36.6 C. e. From May 1, 2019 to May 17, 2019: 13 out of 13 days at 36.7 C. 4. The laboratory technical supervisor confirmed on May 24, 2019 at 11:40 AM, that the cuvette temperature records showed temperatures out of the manufacture's limits and no corrective actions were documented those days.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Dimension EXL system manufacturer's instructions, Dimension Cuvette record temperature review (year 2019) and technical supervisor interview on May 24, 2019 at 11:40 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the routine chemistry tests by the Dimension EXL system from January 2, 2019 to May 17, 2019. Refer to D 5405. (The laboratory failed to follow the Dimension EXL manufacturer's instruction when 100 percent patients specimens were processed and reported for routine chemistry tests by the Dimension EXL system from January 2, 2019 to May 17, 2019).
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 Dimension EXL system manufacturer's instructions, Dimension Cuvette record temperature review (year 2019) and technical supervisor interview on May 24, 2019 at 11:40 AM, it was determined that the technical consultant failed to ensure compliance with the analytic system requirements for the routine chemistry tests by the Dimension EXL system from January 2, 2019 to May 17, 2019. Refer to D 5405. (The laboratory failed to follow the Dimension EXL manufacturer's instruction when 100 percent patients specimens were processed and reported for routine chemistry tests by the Dimension EXL system from January 2, 2019 to May 17, 2019).
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate 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 Dimension EXL system manufacturer's instructions, Dimension Cuvette record temperature review (year 2019) and technical supervisor interview on May 24, 2019 at 11:40 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D 5405. (The laboratory failed to follow the Dimension

	EXL manufacturer's instruction when 100 percent patients specimens were processed and reported for routine chemistry tests by the Dimension EXL system from January 2, 2019 to May 17, 2019).