Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0669071	12/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
2080 Century Park Laboratory	2080 Century Park East Ste 1410, Los Angeles, CA	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient, quality control & proficiency testing records, lack of annual test accuracy verification records and interview with the laboratory technical consultant on December 29, 2021 at 1:44 pm, the laboratory failed to verify, at least twice annually, the accuracy of its CTX-I test for the years of 2020 and 2021. The findings include: 1. The laboratory performed CTX-I test using IDS iSYS system. However, the laboratory did not have any documentation showing that it had verified its test accuracy, at least twice annually for the years of 2020 and 2021. Hence, the accuracy of the reported CTX-I results could not be assured and potentially harmed patients. 2. The laboratory technical consultant on December 29, 2021 at 1:44 pm, affirmed that the laboratory did not verify the accuracy of its CTX-I test, twice yearly. 3. The laboratory's testing declaration form, signed by the laboratory Director on 12/29/2021, stated that the laboratory performs 660 CTX-I tests, annually.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

	applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, establishment & verification of test performance specifications, patients test records and interview with the laboratory technical consultant on December 29, 2021 at 12:10 pm, the laboratory failed to establish and verify the performance specifications of HBA1C and HDL tests. The findings include: 1. The laboratory performed HBA1C and HDL tests using reagents from Caldon Biosciences on Beckman AU480 instrument which is not FDA approved. Moreover, the laboratory did not establish and verify the required test performance specifications. Therefore, the accuracy and the validity of the reported HBA1C and HDL tests results generated using Caldon Biosciences reagent can not be assured. 2. The laboratory technical consultant on December 29, 2021 at 12:10 pm, affirmed that Caldon Biosciences reagent is not FDA approved, and the laboratory did not establish and verify the required test performance specifications. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/29/2021, stated that the laboratory performs about 10,000 tests, annually.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient test records, and interview with the laboratory technical consultant on December 29, 2021 at 12:40 pm, the laboratory failed to immediately alert the ordering physician after determining the panic value of the BNP test for the patient # M9460 causing potential harm to the patient. The findings include: 1. The laboratory received the patient specimen, ID 402484 on 12/14/2021 at 16:31. The laboratory's test record printed on 12/14/2021 at 16:47 showed BNP test results in handwriting. The instrument printout paper showed the date as 12/12/21 for which the laboratory did not set the correct date. The laboratory's note on the test report showed that the staff notified the doctor on 12/15 /21 and did not have a time. The laboratory records should document the date, time, and person to whom the test results were reported. 2. The laboratory technical consultant on December 29, 2021 at 12:40 pm, affirmed that the laboratory did not immediately notify the ordering doctor after determining the panic value. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/29/2021, stated that the laboratory performs 1,211 BNP tests, annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, establishment & verification of test performance specifications, patients test records and interview with the laboratory technical consultant on December 29, 2021 at 12:10 pm, the laboratory director failed to ensure that the verification procedure used for the HBA1C and HDL tests was adequate. The findings include: See D5423.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient, quality control and test accuracy verification records, and interview with the laboratory technical consultant on December 29, 2021 at 1:44 pm, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the CTX-I, HBA1C and HDL tests. See D5217 and D5423.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, establishment & verification of test performance specifications, patients test records and interview with the laboratory technical consultant on December 29, 2021 at 12:10 pm, the laboratory technical consultant failed to establish the laboratory's HBA1C and HDL tests performance characteristics. The findings include: See D5423.