Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0669071	09/25/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with the Technical Consultant (TC), the laboratory failed to establish written policies and procedures to assess employee competency. The findings include: 1. The laboratory's Technical Consultant affirmed on September 25, 2024, at approximately 1:30 pm, that the laboratory did not have written policies and procedures to assess employee competency. 2. The laboratory's testing declaration form, signed by the laboratory director on September 25, 2024, stated that the laboratory performed approximately 479,419 tests annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials

	having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview with the Technical Consultant (TC) and review of Chemistry Quality Control (QC) records from April 2023 through September 2024, the laboratory failed to verify the stated values of the commercially assayed chemistry QC materials in use at the time of the survey. The findings include: 1. It was the practice of the laboratory to use BIO-RAD commercially assayed chemistry QC materials (Lyphocheck) to monitor patient chemistry testing using Beckman Coulter AU480. The technical consultant stated that on April 25, 2023, the laboratory switched the QC materials from the old lot number 89710 (L1: 89711 and L2: 89712) to the new lot number of 89730 (Level 1: 89731 and level 2: 89732). 2. The laboratory maintained no documentation to indicate the stated values of chemistry QC materials lot number 89730 had been verified for Beckman Coulter AU480 instrument by the laboratory prior to testing patient samples. 3. On September 25, 2024, at approximately 2:30 pm, the technical consultant affirmed that the laboratory did not verify the value of QC materials provided by the manufacturer. 4. The laboratory did not verify the Chemistry QC materials for 17 of 17 months. The laboratory's testing declaration form, signed by the laboratory director on September 25, 2024, stated that the laboratory performed 310,721 chemistry tests annually.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 interview with Technical Consultant (TC), review of laboratory's policies and procedures manuals, Quality Control (QC) records, and Proficiency Testing (PT) records, it was determined that the Laboratory Director (LD) failed to ensure that established quality control procedures were followed, approved corrective action was taken for unacceptable and unsatisfactory PT scores, and the accuracy of the unregulated analytes was verified twice annually. The findings include: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for routine chemistry testing using Beckman Coulter AU480 instrument. According to the API evaluation, the laboratory failed to attain a score of at least 80% of acceptable responses for each analyte in each testing event and failed to take the necessary corrective action. The laboratory attained a score of 0% for High-density Lipoprotein (HDL) in the second event of 2023, which indicated unsatisfactory analyte performance for the testing event and did not take corrective action. 2. The laboratory participated in the API proficiency testing program for Partial Thromboplastin Time (PTT) testing using INSTRUMENTATION LABORATORY

	IL ACL 6000. API evaluations showed that the laboratory attained a score of 80% in the 2nd and 3rd events of 2022, the 2nd and 3rd events of 2023, and the 1st event of 2024. The laboratory failed to take corrective action for the unacceptable analyte scores. On September 25, 2024, at approximately 12:20 pm, the technical consultant affirmed that the laboratory did not take corrective actions for the unacceptable analyte scores. 3. The laboratory performed Free Triiodothyronine (FT3) and Unsaturated Iron-Binding Capacity (UIBC) testing using Beckman Coulter Access 2 instrument, which are not listed under Subpart I of 42 CFR part 493. The laboratory chose to enroll in the API proficiency testing program to verify the accuracy of these tests. However, the laboratory did not attain a score of at least 80% twice annually in 2022 for FT3 and UIBC. On September 25, 2024, at approximately 12:20 pm, the technical consultant affirmed that the laboratory did not verify accuracy of the test for FT3 and UIBC at least twice annually in 2022. 4. The laboratory performed the Collagen Type I C-Telopeptide (CTX-1) test using Immunodiagnostic Systems (IDS iSYS), which is not listed under Subpart I of 42 CFR part 493. The laboratory failed to verify the accuracy of the test at least twice annually for 3 of 3 years. On September 25, 2024, at approximately 12:30 pm, the technical consultant affirmed that the laboratory did not verify the test accuracy of CTX-1 for the years 2022, 2023, and 2024. 5. The laboratory failed to verify the stated values of the commercially assayed chemistry QC materials for the new QC lot. See D5469. 6. The laboratory failed to establish written policies and procedures to assess employee competency. See D5209. 7. The laboratory's testing declaration form, signed by the laboratory director on September 25, 2024, stated that the laboratory performed approximately 479,419 tests annually. Thus, the reliability and quality of the patient results reported cannot be assured.