Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2141585	**(X3) Date Survey Completed** 01/04/2023
Name of Provider or Supplier Sc Health Labs	**Street Address, City, State** 15540 Rockfield Blvd Suite A100, Irvine, 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**
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 test validation results, and interview with the laboratory technical supervisor on January 4, 2023, at 12:20 pm, the laboratory failed to establish analytical sensitivity for its drug tests. The findings include: 1. The laboratory used an in house developed test to detect various drugs using LC-MS/MS method. However, it did not determine the analytical sensitivity. The technical supervisor said that it used the cut off value which was predetermined and was obtained from his previous lab. The laboratory is responsible for determining the lowest concentration or amount of the analyte or substance that can be measured or distinguished from a blank, i.e., minimum detection limits or how much of the analyte must be present to be measured. Therefore, the cut off values used by the laboratory could not be assured and might have harmed patients. 2. The laboratory technical supervisor on January 4, 2023, at 12:20 pm, affirmed that the laboratory did not determine the analytical sensitivity. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/28/2022, stated that the laboratory performs approximately 90,000 toxicology tests, annually.

D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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--When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory ' s quality control material, calibrator, and interview with the laboratory technical supervisor on January 4, 2023, at 11:10 am, the laboratory failed to use different lot ' s control material from the calibrator. The findings include: 1. The laboratory used an LC-MS/MS method to detect various drugs in the patient sample. It generates a standard curve each time of testing. The laboratory used a calibrator to generate the standard curve, however, it always used the calibrator material from the same lot as quality control material. Therefore, the validity of the test method can not be assured and might have harmed patient. 2. The laboratory technical supervisor on January 4, 2023, at 11:10 am, affirmed that the laboratory used the calibrator material from the same lot as quality control material. 3. The laboratory ' s testing declaration form, signed by the laboratory director on 7/28 /2022, stated that the laboratory performs approximately 90,000 toxicology tests, annually.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 test validation results, quality control materials, and interview with the laboratory technical supervisor on January 4, 2023, at 12:20 pm, it was determined that the laboratory director failed to assure test validity by establishing the test performance characteristics including the quality control. The findings include: See D5467 and D5423.