Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2198285	12/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ucla Swabseq Covid 19 Testing Lab	650 Charles E Young Dr S, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Analytic System was not met. The findings include: The laboratory failed to obtain necessary supplemental Emergency Use Authorization (EUA) for its modified COVID-19 test from the Food and Drug Administration (FDA). The FDA requires the laboratory submit COVID-19 test validation data for review before implementing the test to the patients. Moreover, the laboratory has been providing the test to asymptomatic college and high school students without establishing a reference range in this patient population that reflects the type of specimen and demographic variables such as age and sex. See D5423.
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, Emergency Use Authorization (EUA) documentation from the Food and Drug Administration (FDA), establishment & verification of test performance specifications, patients test records and interview with the laboratory general supervisor on December 9, 2021 at 1:30 pm, the laboratory failed to establish and verify reference values for the laboratory's patient population and obtain the required approval from FDA for its modified COVID-19 EUA test. The findings include: 1. The laboratory received an EUA from FDA on October 6, 2020 for its SwabSeq COVID-19 diagnostic test in which upper respiratory specimens were used from individuals suspected of COVID-19 by their health care providers. According to the approved EUA, the swab specimens are subjected to nucleic acid extraction and thereafter, detection with the Next-Generation Sequencing (NGS) technique. The laboratory modified the approved EUA by eliminating the nucleic acid extraction step and adding saliva specimens as preferred sample type. However, the laboratory did not submit its modified COVID-19 test validation data for FDA review and receive a supplemental EUA. The FDA requires that the laboratory submit a supplemental EUA request if it modifies an authorized COVID-19 test. The FDA did not evaluate the laboratory's modified saliva test performance. Moreover, it has been providing the test to asymptomatic college and high school students without establishing a reference range in this patient population that reflects the type of specimen and demographic variables such as age and sex. The laboratory must establish a reference range that is appropriate for the laboratory's patient population. Therefore, the accuracy and the validity of the reported COVID-19 test results utilizing modified EUA can not be assured. 2. The laboratory general supervisor on December 9, 2021 at 1:30 pm, affirmed that the laboratory did not obtain a supplemental EUA for its modified COVID-19 test. 3. The laboratory's testing declaration form, signed by the laboratory Director on 12/03/2021, stated that the laboratory performs about 1,000,000 tests, annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies found during an onsite survey on December 9, 2021 and the severity of the cited deficiencies, it was determined that the laboratory director failed to provide the direction on the analytical phase of COVID-19 testing and fulfill the director's responsibilities. Findings include: 1. The laboratory director failed to ensure that the modified COVID-19 test methodologies selected have the capability of providing the quality of results required for patient care. See D6085. 2. The laboratory director failed to ensure that the verification procedures used for the modified COVID-19 test are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. See D6086. 3. The laboratory director

	failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the modified COVID-19 test system. See D6095.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. 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 general supervisor on December 9, 2021 at 1:30 pm, the laboratory director failed to ensure that the modified COVID-19 EUA test had the capability to provide accurate and reliable results. The findings include: The laboratory was granted an EUA for its COVID-19 test from the FDA. However, the laboratory modified the approved EUA and did not obtain a supplemental EUA with the modification. The FDA did not evaluate if the modified method has capability to provide accurate quality results. Hence, the results generated by this modified method might not be accurate. See D5423.
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 policy & procedure, establishment & verification of test performance specifications, patients test records and interview with the laboratory general supervisor on December 9, 2021 at 1:30 pm, the laboratory director failed to ensure that the verification procedure used for the COVID-19 saliva test was adequate. The findings include: The laboratory was granted an EUA for its COVID-19 test for swab samples from the FDA. However, the laboratory modified the approved EUA and used it for saliva sample. The laboratory did not submit its saliva test validation data to the FDA for evaluation and to obtain a supplemental EUA with the modification before implementing the modified COVID-19 test. Moreover, the laboratory has been providing the test to asymptomatic college and high school students without establishing a reference range in this patient population that reflects the type of specimen and demographic variables such as age and sex. Therefore, the accuracy of the saliva COVID-19 test can not be assured. See D5423.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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, establishment & verification of test performance specifications, patients test records and interview with the laboratory general supervisor on December 9, 2021 at 1:30 pm, the laboratory director failed to maintain an acceptable level of analytical performance for its COVID-19 test. The findings include: The laboratory was granted an EUA for its COVID-19 test from the FDA. However, the laboratory modified the analytical method of the approved EUA by eliminating the nucleic acid extraction step, and thus failed to maintain test analytical performance. See D5423.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and 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 general supervisor on December 9, 2021 at 1:30 pm, the laboratory technical supervisor failed to establish the laboratory's COVID-19 saliva test performance characteristics. The findings include: See D5423.