Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2141174	08/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Curative Labs Inc	605 E Huntington Dr, Monrovia, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Facility Administration was not met. The findings include: 1. The laboratory failed to have adequate space necessary for conducting specimen accessioning and processing (preanalytic) and preparation of positive controls (analytic). See D3001. 2. The laboratory failed to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was minimized. See D3003. 3. The laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. See D3011.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

	This STANDARD is not met as evidenced by: Based on surveyors observation of preanalytic/analytic areas and interviews with the laboratory director (LD), technical supervisor (TS), and testing personnel (TP) on August 13, 2020 at approximately 10:30 a.m. it was determined that the laboratory space was not adequate to process 20,000 patients' samples per day in the preanalytic and analytic phases of the testing for SARS-CoV-2 detection. Findings include: 1. During the laboratory tour on August 13, 2020 at approximately 09:45 a.m. the surveyors observed and determined that the working space for preanalytic (specimen accessioning and processing) work was not adequate for the number of TP working in this area. a. The laboratory sample receiving-processing area of an estimated size of 3,000 sq.ft. was crowded with: approximately 30-40 TP receiving and processing specimens under the Biosafety cabinets, non-TP (maintenance staff for the removal of biohazard waste and miscellaneous non-biohazard waste), and traffic of other staff entering and exiting the room. b. There were more than one or two TP processing specimens side by side using the same Class II Biosafety Cabinet (BSC); an already crowded BSCs with processed specimens, opened sample bags, reagents, and accessioning computers. c. The specimen receiving, accessioning, and processing room consisted of a large, opened space room that served also as access to the stairway leading to the second floor testing rooms, donning and doffing of PPE, storage and pick up of waste material, and a partitioned area for sample preparation. 2. During the laboratory tour at approximately 11:00 a.m. the surveyor observed that the positive control (matrix spiked with pooled SARS-CoV-2 positive patients' samples) "spike room" was used as a general storage area for processed samples. Findings include: a. Seven TP were observed in the room putting away unlabeled boxes of processed patients' specimens. b. Unlabeled positive or negative specimen tubes were stored in opened plastic containers filled to the rim of the container in the room. c. Under the BSC used to spike the positive control were numerous smaller plastic and paper boxes more than halfway filled with previously tested samples and thus, this specific analytic work area of the laboratory had not been maintained to ensure the space necessary for conducting the positive control preparation. 3. During an interview on August 13, 2020 at approximately 11:30 a.m. the LD and TS confirmed that the space for sample processing is inadequate for the amount of TP in the room at the same time and volume of samples processed daily. 4. The LD confirmed on August 13, 2020 at approximately 11:40 a.m. that the positive control "spike room" is also used for storage of numerous already resulted sample containers due to lack of space for storage. 5. The laboratory's testing declaration form, signed by the LD on August 13, 2020, stated that the laboratory performs 2,500,000 tests annually.
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on surveyor observation during the laboratory tour and interviews with the laboratory director (LD), technical supervisor (TS, and testing personnel (TP) on August 13, 2020 it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during testing for the presence of SARS-CoV-2 by the Polymerase Chain Reaction (PCR). Findings include: 1. During the laboratory tour at approximately 09:50 a.m. the surveyor

	observed lack of decontamination at various times during specimen receiving and processing. a. Patients' specimen submitted from numerous collection sites for testing were received in different forms of packaging: non-labelled plastic bags, biohazard labeled plastic bags, plain not labelled boxes, properly labelled UN 3373 boxes, and plastic containers which were not decontaminated before opening to retrieve the individually bagged specimens. b. During sample processing under the BSC, the surveyors observed TP1 grabbed a single bag containing the specimen from the shipment container; decontaminated the outside of the bag, and teared the bag opened. Even though the absorbent paper inside the bag was moist, TP1 did not further decontaminate the bag and left the bag opened while specimen processing continued. c. The torn-opened bags were placed on top of each other and next to the rack containing the recently 70% ethanol decontaminated tubes containing the specimen to be tested. 2. During an interview on August 13, 2020 at approximately 1:45 p.m. the TS and LD confirmed the laboratory failed to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for testing of the presence of SARS-CoV-2 by the Polymerase Chain Reaction (PCR). 3. The laboratory's testing declaration form, signed by the LD on August 13, 2020 at approximately 2:00 p.m. stated that the laboratory performs 2,500,000 tests annually.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyors observation of specimen processing during tour of the laboratory, review of the laboratory's policies & procedures (P&P), record review of 107 patient from April 3, 2020 to August 13, 2020, and interviews with the laboratory technical supervisor (TS) and testing personnel (TP) on August 13, 2020 it was determined that the laboratory failed to establish biosafety protocols based on risk assessment. The laboratory failed to make accessible to all employees and observe biosafety procedures to ensure protection from biohazardous materials. The laboratory had 80 out of 400 staff tested positive for SARS-CoV2/COVID19 PCR test. Findings include: 1. Based on surveyors observation of specimen processing at the time of the laboratory tour on August 13, 2020 at approximately 10:00 a.m., safety procedures to ensure protection from biohazard material were not accessible and observed by laboratory staff. a. Personal Protective Equipment (PPE): coats, gloves, goggles were not worn by all staff entering the SARS-CoV-2/COVID19 sample receiving-processing area. b. Laboratory TP returning from breaks and maintenance staff entered the sample accessioning area through the emergency exit door leading to the parking lot/street without appropriate PPE while sample processing was taking place in the Biosafety cabinets (BSC) next to the emergency door. c. The laboratory did not have a separate area for specimen receiving; both specimen receiving and specimen processing were performed in the same room. Couriers delivered patient's specimens while TP processed specimens in the same room. d. Large Biohazard labelled containers had no lids and were open at all times located at both the sample receiving-processing area and sample testing rooms. e. Processed specimens bags without any further decontamination were taken in bundles out of the BSC and discarded in an opened (no lid) Biohazard labeled container. f. Full biohazard bags were taken out of the biohazard container to be discarded by waste management outside the building

	without decontamination. 2. Based on the surveyors observation during tour of the facility on August 13, 2020 at approximately 10:45 a.m. access to specimen accessioning, processing, and testing area took place through the same door located in the main opened, large room where all personnel passed through while initial sample processing was taking place. 3. Based on the surveyors records review of 107 patients records from April 3 to August 13, 2020 revealed 80 laboratory staff have tested positive for SARS-CoV-2 since testing began at the facility on April 1, 2020. 4. During the surveyors review of the laboratory's policies and procedures the laboratory failed to establish and make accessible biosafety protocols based on risk assessment to all the laboratory staff. 5. When interviewed on August 13, 2020 at approximately 10: 15 a.m. the laboratory TS and TP affirmed that laboratory failed to establish, make accessible, and observe biosafety procedures to ensure protection from biohazardous materials.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyors observation at the time of the laboratory tour, review of the laboratory's policies and procedures, and interview with the laboratory director, technical supervisor, and testing personnel; it was determined that the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as speciefied in 493.1249.for each specialty and subspecialty of testing performed. See D 5311 and D5391.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the surveyors observation, review of laboratory's written policies and procedures (P&P), and interviews with the laboratory director (LD) and the technical supervisor (TS) the laboratory failed to establish written policies and procedures for specimen labelling, specimen storage and preservation, and specimen transportation. Findings included: 1. Based on the surveyor review of P&P on August 13, 2020 at approximately 5:00 p.m., no written P&P were found on the following observed procedures during the laboratory tour on the day of the survey: a. The laboratory accessioning staff received patients' specimens by scanning tubes labeled with the

	patients' demographics encoded in bar codes that were issued at the place of specimen collection. No written P&P for specimen labeling was available at the time of the survey. b. After sample processing, SARS-CoV-2 detection by RT-PCR, and after reporting of results, samples were stored at different locations, different temperatures; room temperature, frozen, or refrigerated. No written P&P on specimen storage and preservation was available at the time of the survey. c. Samples were submitted daily from multiple locations from all over the nation in different packaging materials: boxes, plastic bags, plastic containers, etc. No written procedure was available on specimen packaging and transportation. 2. Based on an interview with the LD and TS on August 13, 2020 at approximately 5:45 p.m. it was confirmed that the laboratory failed to maintain written P&P on specimen labeling, storage and preservation, and packaging and transportation. 3.. According to laboratory records, the laboratory performed approximately 2,500,000 patient tests annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyors interviews with the laboratory director (LD) and laboratory testing personnel (TP) and record review of pre-analytic remedial action records on August 13, 2020, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's preanalytic systems when received patient specimens did not meet the laboratory's criteria for acceptability. Findings included: 1. According to laboratory TP, during the accessioning of patient specimens, if a patient specimen was received that did not meet the laboratory's criteria for acceptability, a description as to why the specimen did not meet the laboratory's criteria for acceptability would be electronically documented, applicable collecting site would be notified, appropriate corrective actions would be taken and noted electronically, and the incident would be captured for quality assessment review. 2. Based on surveyor review of policies and procedures on August 13, 2020 at approximately 6:00 p.m. it was determined that the laboratory failed to maintain written policies and procedures detailing the quality assessment process described. 3. According to the LD declaration statement, the laboratory performed approximately 20,0000 patient tests daily.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory supplies and reagent materials used for decontamination and interview with the laboratory director (LD) and testing

	personnel (TP), it was determined that the laboratory failed to label the decontamination reagents to indicate the preparation and expiration dates when such reagents are used to decontaminate surfaces where approximately 20,000 specimens per day are processed for SARS-CoV-2 RNA detection. The findings included: 1. Based on surveyor observation during the laboratory tour on August 13, 2020 at approximately 11:30 a.m. TP used in-house prepared 70% ethanol and 1:10 sodium hypochlorite (bleach) to decontaminate BSC, specimen racks, and surfaces working areas with no preparation or expiration date labels for which the effectiveness of the decontamination reagents cannot be assured. a. The decontaminating reagents that were in-use at the time of the survey located on the positive control preparation and RNA extraction rooms were not labeled to indicate preparation and expiration dates. According to the laboratory established protocols 1:10 bleached is to be prepared daily and 70% Ethanol expires within 180 days of preparation. 2. The laboratory TP affirmed in an interview conducted August 13, 2020 at approximately 2:00 p.m. that the decontaminating reagents were not labeled with preparation and expiration dates. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 20,000 samples per day.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, lack of maintenance protocol, and interview with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to establish a maintenance protocol for the AIR Clean Biosafety cabinets (BSC) that ensures its continued performance after installation necessary for accurate and reliable test results. The findings included: 1. Based on surveyor observation during tour of the laboratory on August 13, 2020 at approximately 12:00 p.m. TP used approximately 20 AIR Clean BSC located at various laboratory sections for the detection of SARS-CoV-RNA in patients' specimens at different times in preparation for the PCR method: RNA extraction, preparation of Master Mix, and application of sample template. No records of TP following a established policy of maintenance protocol for the AIR Clean BSC was found. 2. During the surveyor document review of the laboratory's AIR Clean BSCs it was determined that all AIR Clean BSC (Serial number AC632LFVC-51214 and approximately 19 more BSCs) had no evidence of maintenance protocol or certification policy. 3. The LD confirmed on an interview on August 13, 2020 at approximately 4:00 p.m. that the laboratory failed to establish a maintenance protocol for the AIR Clean cabinets used in molecular testing. 4. Based on the laboratory's monthly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 20,000 sample daily.
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 August 13, 2020 and the severity of the cited deficiencies, it was determined that the laboratory director failed to provide overall management and direction on the preanalytical phase of testing. Findings include: 1. The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. See D6082. 2. The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. See D6083. 3. The laboratory director must provide a safe environment in which employees are protected from physical, chemical, and biological hazards. See D6084. 4. The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. See D6106.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on surveyor document review and the lack of documentation to establish policies and procedures to ensure that cross-contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for testing of the presence of SARS-CoV-2 by the Polymerase Chain Reaction (PCR) method were minimized (D3003); written policies and procedures for specimen labeling, specimen storage and preservation, and specimen transportation (D5311); failure to establish and follow written policies and procedures for and ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems (D5391) and fail to establish maintenance protocol for all AIR Clean Biosafety cabinets (5433); it was determined that the laboratory director failed to ensure that testing systems developed and used for SARS-CoV-2 PCR detection performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing in a safe environment.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by:

	Based on surveyors direct observations of the laboratory's SARS-CoV-2 testing processes and interview with the technical supervisor (TS) and testing personnel (TP) on August 13, 2020; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed. Findings include: See D3001 and D3003.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on the survey findings and deficiencies cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure a safe environment in which personnel are protected from biohazardous materials. Findings include: See D3011
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's written policies and procedures and interviews with the laboratory director (LD) and the technical supervisor, it was determined that the LD failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. The laboratory had no written procedure for specimen processing and handling. Findings include: See D5311