Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2204020	04/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Shield T3 Llc	1252 Orleans Dr, Sunnyvale, 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 receiving, accessioning, and processing (preanalytic), preparation of positive controls, addition of sample template, and polymerase chain reaction (PCR) testing (analytic) and analysis and interpretation of test results (postanalytic). 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 ensure that the molecular amplification procedures that are not contained in closed systems have unidirectional flow for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection. See D3005.
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 observation of the laboratory testing area (one trailer with external refrigerated air supply) and interview with the technical supervisor (TS), general supervisor (GS), and testing personnel (TP); it was determined that the laboratory testing area failed to provide adequate space, ventilation, and utilities necessary for conducting all phases of the clinical testing process. The findings included: 1. The laboratory area consist of a trailer of approximately 700 square feet in which specimen receiving, sample processing, preparation of reagents and controls, addition of sample template, reading, and analyzing of test results for the detection of SARS-CoV-2 by the polymerase chain reaction (PCR) took place. 2. The space for the testing personnel (about 6 TP), biosafety cabinets, PCR processing sections, and PCR testing equipment (3 Quant Studio instruments) is very limited and all sections are next to each other . The testing area is crowded where TP bump into each other, it is difficult to maintain, and fail to provide sample integrity and quality of testing. In addition, the proximity of testing areas increases the risk of sample cross contamination. 3. The TS, GS, TP affirmed on April 12, 2021 at approximately 11:00 a.m. that the laboratory testing space , fails to provide adequate working areas, ventilation, and utilities for conducting all phases of the testing process: preanalytical, analytical and postanalytical. 4. The laboratory's testing declaration form, signed by the laboratory director on April 12, 2021, stated that the laboratory performs approximately 750,000 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 interview the technical supervisor (TS) and general supervisor (GS) on April 12, 2021; it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen receiving and processing. Findings include: 1. During the laboratory tour at approximately 11:00 a.m. the surveyor observed the area assigned for sample receiving and processing to be a very restricted area. The samples were received through a small window where the following took place: a. The TP receiving the specimens tore the biohazard bag open containing a tube with raw saliva sample in an opened bench. b. The biohazard bag was not decontaminated before or after removal of the tube containing the sample. c. Samples were then placed in a glass container with 3% hydrogen peroxide (H2O2) on the same opened bench where specimen receiving took place. d. There was no record of when or how the H2O2 was prepared. e. No change of gloves was observed when transferring samples to the heated water bath for deactivation. 2. Preparation of the master mix, positive controls, and addition of sample template took place in the same Biosafety Cabinet (BSC): a. Even though there was a decontamination log, the surveyor observed transferring of samples and code scanning samples continously disturbing the laminar flow in the BSC. b. Change of gloves did not take place between addition of template from one plate to another. 3. During an interview on April 12, 2021 at approximately 11:45 p.

	m. the TS and GS confirmed the laboratory failed to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies when processing in both an opened bench and under the BSC. 4. The laboratory's testing declaration form, signed by the laboratory director on April 12, 2021stated that the laboratory performs 750,000 tests annually during two 10 hours shifts Monday through Friday .
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 detection by the Polymerase Chain Reaction (PCR) testing, and interviews with the technical supervisor (TS), general supervisor (GS) and testing personnel (TP) on April 12, 2021 for its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures that are not contained in closed systems have unidirectional flow for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection. The findings included: 1. The laboratory performs PCR testing for the presumptive detection of SARS-CoV-2 in saliva using the covidSHIELD a modification of the EUA Thermo Fisher Scientific Applied Biosystems TaqPath COVID-19 Combo Kit. 2. During the laboratory tour on 04/12/2021 at approximately 11:00 a.m. the surveyor observed that storage and preparation of reagents, RNA extraction, and PCR reaction using the QuantStudio were all performed in the same room with no unidirectional flow. In addition, preparation of reagents for the PCR Master Mix cocktail, positive control, and addition of sample template were performed under the same Biosafety cabinet. 3. The TS, GS, and TP confirmed by interview on April 12,2021 at approximately 11:45 a.m. that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in separate areas with unidirectional flow rooms. 4. Based on laboratory records, the laboratory performed and reported approximately 750,000 Virology (COVID-19) molecular diagnostic tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of a proficiency testing report, lack of documentation for corrected action, and interview with the laboratory's general supervisor (GS), it was determined that the laboratory failed to document corrective action of all proficiency testing evaluation and verification activities which must be documented. The findings included: 1. The laboratory developed for proficiency testing at the time the laboratory first started testing for the presence of SARS-CoV-2, an in-house developed blinded samples proficiency. a. From five (5) blinded samples consisting of two (2) positive and three (3) negative samples tested; the laboraory failed one (1)

	positive sample for the detection of SARS-CoV-2. b. At the time of the survey documentation of proficiency tests results data, corrective action taken, signature and date of the laboratory director's review was not documented. 2. The GS confirmed on April 12, 2021 at approximately 1:00 p.m. that the laboratory had no documentation of corrective action and had not established, or followed written policies and procedures to monitor and correct problems that may occur. 3. For ten (10) out of ten (10) random patient test results reviewed covering the period from 12/14/2020 to 3/31 /2021, the laboratory analyzed and reported approximately 250,490 tests for which the accuracy of the results could not be assured.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of ten (10) random patient sampling covering a period from 12/14 /2020 to 3/31/2021, review of quality control documents, preventive maintenance, quality assurance, and interview with the laboratory's general supervisor (GS) and testing personnel (TP); it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. The findings included: 1. On the day of the survey 04/12/2021at approximately 3:00 p.m.. no documentation could be retrieved to show that the laboratory had written policies and procedures for quality control failures, preventive maintenance, and quality assessment and assurance. This correction process involves policies for quality assessment and assurance, and policies for preventing problems that have been identified. 2. The GS and TP confirmed on 04/12/2021 at approximately 1:30 p.m. that the laboratory did not have written policies and procedures that reflect the current practice for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. 3. The testing declaration submitted on 04/12/2021 estimated 750,000 tests performed annually.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures (P&P), test requisition, ten (10) randomly chosen patients records from 12/14/2020 to 3/31/2021, and interview with the laboratory technical supervisor (TS), general supervisor (GS) and testing personnel (TP); the laboratory's test requisition failed to include the name and address or other suitable identifiers of the authorized person requesting the test, the name and address of the specimen submitter, and a contact person to enable the reporting of laboratory results. The findings include: 1. The laboratory used electronic coded labels as identifiers which were scanned to download patient demographics data; however, the test requisition did not have any other information including the name of the authorized person who ordered the test. 2. On April 12, 2021 at approximately 5:00 pm the laboratory's TS, GS, and TP affirmed that the laboratory did not have a complete test requisition for the ten (10) randomy chosen patients reviewed. 3. The laboratory testing declaration form, signed by the laboratory director on April 12, 2021, indicated that the laboratory performs approximately 750,000 tests annually.
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 technical supervisors (TSs) and general supervisor (GS) the laboratory failed to establish written policies and procedures for specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, and reporting final results to the State. Findings included: 1. Based on the surveyor review of P&P on April 12, 2021 at approximately 2:00 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. Sample decontamination with 3% Hydrogen peroxide and heat incativation of the saliva sample took place right after specimen retrieval from the biohazrd bags containing individual samples. No written P&P for specimen decontamination and deactivation were available at the time of the survey. c. Samples were submitted daily from multiple locations from all over Northern California and various States in different packaging materials unlabaled plastic bags, plastic containers, etc. No written procedure was available on specimen packaging and transportation. 2. Based on an interview with the TSs and GS on April 12, 2021 at approximately 4:00 p.m. it was confirmed that the laboratory failed to maintain written P&P for specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, and

	reporting final results of positive and negative SARS-CoV-2 as mandated by the State of California. 3. According to laboratory records, the laboratory performs approximately 750,000 saliva patient samples for the detection of SARS-CoV-2 tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation on the lack of protection of equipment and instruments from fluctuations and interruptions in electrical current and interviews with the technical supervisor (TS) and general supervisor (GS); it was determined that the laboratory failed to provide protection of instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. The findings included: 1. On the day of the survey, 04/12/2021 based on observation and interview with the TS and GS the laboratory failed to provide documentation for the instruments electrical fluctuation back up in which electrical fluctuations and black outs might have occurred affecting proficiency and patient testing. 2. The TS and GS confirmed on 04/12/2021, at approximately 6:00 p.m. that the laboratory has no protection of equipment (2 Quant Studios in use) and instruments from fluctuations and interruptions in electrical current. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 2,285 test daily.
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 the surveyor's observation, lack of maintenance protocol and documentation, and interview with the technical supervisor (TS) and general supervisor (TS); it was determined that the laboratory failed to establish and document a maintenance protocol for the heating bath, vortex, and thermometers, that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. The laboratory used small equipment such as heating block and vortex for processing saliva samples for the detection of SARS-CoV-2 and digital thermometers with no maintenance or calibration records. 2. Based on surveyor observation during

	tour of the laboratory tour on April 12, 2021 at approximately 11:00 a.m. the equipment described above used in the laboratory had no records of maintenance. 3. The TS and GS affirmed that the laboratory failed to establish a maintenance protocol the small equipment described in 1. 4. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 750,000 samples annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of equipment function check documentation from December 14, 2020 to February 25, 2021, ten (10) randomly selected patient test results from the same time period, and interviews with the laboratory's technical supervisors (TSs), and general supervisor (GS); it was determined that the laboratory failed to ensure function checks were performed and documented. No documentation could be retrieved for temperature checks of the heating bath, refrigerators, and freezers; no quality control records (QC) , or preventive maintenance (PM) of the equipment used for patient testing for the period cited. The findings included: 1. On 04/12/2021 review of the laboratory's temperature checks, QC, and PM logs showed that no documentation was recorded on the equipment function check logs since the laboratory begun testing samples; December 1, 2020 until February 25, 2021, when recording daily temperature, QC, and PM fucntion check logs were implemented. 2. The TS and GS confirmed on 4/12/2021 at approximately 3:30 p.m. the lack of documentation cited above during the interview for the equipment function checks documentation for the randomly chosen patients testing review performed. Patients tests were resulted and reported during this time lacking equipment function checks documentation. 3. The laboratory's testing declaration of 04/12/2021estimated 750,000 patient tests performed 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 April 12, 2021 and the severity of the cited deficiencies, it was determined that the laboratory director failed to provide overall management and direction on all the phases of the laboratory 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 ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services and to identify failures in quality as they occur.See D6094. 4. The laboratory director must specify, in writing, delegation of responsibilities and duties for each supervisor, as well as each person engaged in all the phases of laboratory testing: preanalytic, analytic, and postanalytic. See D6107.
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 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); failure to provide for molecular amplification not contained in close systems unidirectional flow (D3005), failure to have written policies and procedures for collection, specimen labeling, specimen storage and preservation, specimen transportation, and reporting of final results to the State (D5311); failure to establish and document a maintenance protocol for the heating bath, vortex, thermometers and small equipment (5433); and failure to provide protection of instruments from fluctuations and interruption of electrical current; 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 surveyor's direct observations of the laboratory's SARS-CoV-2 testing processes and interview with the laboratory's general supervisor, technical supervisor, and testing personnel on April 12, 2021; 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.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory documnetation records and interview with the laboratory's technical supervisor, general supervisor and testing personnel; it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5291
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records of personnel training, competency evaluation, laboratory policies and procedures, random patient testing records, and interview with the laboratory 's general supervisor (GS); the laboratory failed to provide records showing that the laboratory director (LD) has authorized, delegated, and approved lab personnel of any responsibilities and duties in writing. The findings include: 1. The laboratory did not have any records of written delegation and authorization of responsibilities and duties by the LD for laboratory testing personnel. 2. On April 12, 2021 at approximately 5:00 p.m., the GS affirmed that the LD did not assign, delegated, and authorized in writing duties and responsibilities to the laboratory personnel including the technical supervisors and the general supervisor. 3. The laboratory testing declaration form, signed by the LD on April 12, 2021 stated that the laboratory performs 750,000 tests annually.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on interviews with the general supervisor and testing personnel, review of policies and procedures, and patients' reports; it was determined that the technical supervisor failed to ensure that patient test results were not reported until the test system was functioning properly. See D5221, D5305, and D5435.