Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2119391	04/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Orange Toxicology Lab Inc	1535 South D St, Ste 210, San Bernardino, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) result reports and interview with the laboratory staff, it was determined that the laboratory failed to enroll and participate in a proficiency testing (PT) program that meets the criteria in subpart H of 42 CFR part 493 and is approved by HHS. The findings included: 1. The laboratory performed SARS-CoV-2 RT-PCR (Covid-19) tests and failed to show evidence of enrollment in a PT program for Virology testing events using a CMS approved PT program for 2022 when the laboratory started testing for Covid19. The laboratory analyzed and reported Covid-19 patient test results during the approximate time of non-enrollment in a proficiency testing (PT) program. 2. The laboratory staff confirmed on 4/17/2023 at approximately 3:00 p. m. that patient test results for Covid-19 were reported, yet the laboratory had not enrolled in an accredited PT program for SARS-CoV-2 RT-PCR for the year 2022. 3. The laboratory annual testing declaration (4/18/2023) estimated total volume of 12,000 Covid-19 tests annually.
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 ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was minimized. See D3003. 2. 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.
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 with the testing personnel (TP) and office manager (OM) on April 17, 2023; 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 11:40 a.m. the surveyor observed the area assigned for sample receiving, processing preparation of reagents and quality control, and sample analysis for the Covid19 Direct RT-PCR test took place in the same area /room. 2. During an interview on April 17, 2023, at approximately 12:00 p.m. the TS and OM confirmed the laboratory failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples over the same area/room. 3. The laboratory's testing declaration form, signed by the laboratory director on March 18, 2023, stated that the laboratory performs approximately 12,000 samples annually.
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 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory's testing personnel (TP) and Office manager (OM) on April 17, 2023 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using automated extraction and manual methods for preparation of the master-mixes, controls and reagents, and addition of template. 2. During the laboratory tour on April 17, 2023, at approximately 11:40 a. m.. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same room without unidirectional flow. 3. The OM and TP confirmed by interview on 4/17/2023 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA by "Covid19 Direct RT-PCR" procedure was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 12,000 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.
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 four (4) randomly chosen patient sampling covering a period from 11/16/2022 to 3/15/2023, review of quality control documents, preventive maintenance, quality assurance, and interview with the laboratory's office manager (OM) 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 4/17/2023 at approximately 2:00 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 OM and TP confirmed on 4/17/2023 at approximately 2:30 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 4/18/2023 via email estimated 12,000 tests performed annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on the lack of laboratory written test procedure, review of four (4) randomly chosen patients results, and interview with the laboratory's testing personnel (TP) and office manager (OM), it was determined that the laboratory failed to have current written procedures for SARS-CoV-2 RT-PCR tests performed in the laboratory. The findings included: 1. On the day of the survey on April 27, 2023, at approximately 12: 30 p.m. the laboratory failed to provide the current written procedure for SARS-CoV-2 RT-PCR test performed in the laboratory. 2. For four (4) out of four (4) randomly chosen patient's SARS-CoV-2 test results reviewed covering period from 11/16/2022 to 3/15/2023 patients; no current written tests procedure was available to reflect SARS-CoV-2 RT- PCR test. 3. The OM and TP confirmed on April 17, 2023, at approximately 12:30 p.m. that the laboratory did not have current written procedures available for SARS-CoV-2 RT-PCR test performed in the laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the incomplete laboratory's verification of performance documentation for the high complexity testing SARS-CoV-2 (COVID-19) RNA detection by the Polymerase Chain Reaction (PCR), interviews with the laboratory's testing personnel (TP) and office manager (OM) , and review of four (4) randomly selected patient test records for COVID-19 from 11/16/2022 to 3/15/2023; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory had only documentation to show for determination of accuracy with no raw data by PCR performance specifications prior to reporting patient test results. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy (B) Precision (C) Reportable range of test results for the test system (D) Sensitivity and (E) Specificity. 2. The laboratory was unable to provide for review additional documents using patient samples to establish the performance specifications in 1. 3. The TP affirmed at the time of the survey on 4/17/2023 at approximately 12:00 p. m. that no documents could be retrieved to show that the SARS-CoV-2 RNA detection by PCR performance specifications were performed prior to reporting patient test results when the laboratory went live testing and reporting COVID-19 diagnostic tests. 4. Based on the estimated annual tests volumes reported on 4/18/2023; the laboratory performed and reported approximately 12,000 SARS-CoV-2 (Covid19) tests. The precision and reliability of the reported results could not be assured.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the laboratory's procedure manual, lack of documentation, observation, and interview with the testing personnel (TP) and office manager (OM); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's Biosafety cabinet, small equipment such as vortexes and microcentrifuges, pipettes, and thermometers. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that maintenance and calibration be performed according to manufacturer's requirements on all equipment used in the laboratory. 2. The TP and OM confirmed on April 17, at approximately 11: 30 a.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of laboratory's biosafety cabinet (BSC), small equipment such as vortexes and microcentrifuges, pipettes, and thermometers used in the laboratory. 3. According to the test volume declared by the laboratory on 4/17 /2023 the laboratory performs approximately 12,000 diagnostic tests annually.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be

	qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on the lack of the laboratory personnel records, and interview with the laboratory office manager (OM) for High Complexity Laboratory, review of four (4) randomly chosen patient test results, it was determined that the laboratory director failed to provide documentation to demonstrate qualification to direct a High Complexity Virology Laboratory. The findings included: 1. On the day of the survey, April 17, 2023, the surveyor requested from the laboratory office manager to provide documentation showing the laboratory's director qualification to direct a High Complexity Virology Laboratory. The office manager failed to provide the requested documentation. 2. The qualification of a laboratory director for high complexity testing in the specialty of Virology is specified under 42 C.F.R 493. 1443 (a) thru (b) (5) of this part.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on the laboratory director qualifications and interview with the office manager (OM) it was determined that the laboratory director does not meet the requirements as stated in 493.1455 "Clinical Consultant Qualification" to qualify to be the laboratory's clinical consultant. The findings included: 1. The current laboratory director (LD) holds and earned a doctorate in Chemistry from an accredited institution; therefore, qualified for laboratory director license title as Clinical Chemistry Bioanalyst. b. The LD does not possess any of the medical degrees as stated in 493.1443 to be qualified as clinical consultant. c. The OM confirmed on April 17, 2023, that the LD does not hold a medical degree to meet the required qualifications to be the laboratory's clinical consultant.