Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0642965	07/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
San Diego Reference Laboratory	6565 Nancy Ridge Dr, San Diego, 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 interviews with the laboratory's testing personnel (TP) 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 hematology procedures and failed to show evidence of enrollment in a PT program for hematology subspecialties using a CMS approved PT program for the year 2023. The laboratory analyzed and reported tests for hematology cell blood count (RBC, WBC, hemoglobin, hematocrit, and platelet count) patient test results during the time of non-enrollment in a proficiency testing (PT) program. 2. The laboratory staff confirmed on July 11, 2024, at approximately 1:50 p. m. that patient test results for hematology were analyzed and reported, yet the laboratory had not enrolled in an accredited PT hematology for the year 2023. 3. The laboratory annual testing declaration signed by the LD estimated total volume of hematology 123,255 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 the surveyor's observation during the laboratory tour and interview with the laboratory's testing personnel (TP) and the laboratory manager (LM) on July 11, 2024; it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen processing of samples for the detection of drugs of abuse in urine and saliva. The findings include: 1. During the laboratory tour at approximately 3:15 p.m. the surveyor observed the area assigned for urine and saliva sample accessioning, processing (opening tubes), and sample labelling for drug testing test took place in the same area/desk where the computer was used, and paperwork was manipulated by personnel not wearing personal protective equipment (PPE). 2. During an interview on July 11, 2024, at approximately 3:30 p.m. the LM and TP confirmed the laboratory failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples over the same area not wearing PPE. 3. The laboratory testing declaration form on 7/11/2024 declared by the laboratory manager stated that the laboratory performs approximately 1,471,113 drug testing in urine and saliva samples annually.
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 the surveyors' observation during the laboratory's tour, reagent materials used in the laboratory and interview with the testing personnel (TP); it was determined that the laboratory failed to label various reagents used for decontamination of surfaces to indicate the reagent's name, opening, preparation, and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on July 11, 2024, at approximately 3:30 pm.; no opening, preparation, or expiration date labels were used or documented for various decontamination reagents used throughout the laboratory. 2. The laboratory's TP affirmed in an interview conducted on July 11, 2024, at approximately 3:45 p.m. that the following reagents: wash detergent solution and 2% bleach, were not labeled with the received date, opening, preparation, and expiration dates or documented in a reagent preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 2,081,125 for which decontamination reagents were not labelled.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory tour, examination of laboratory reagents, and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to not store and use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, July 11, 2024, at approximately 4:30 p.m. the surveyors found while touring the laboratory the following reagent used beyond its expiration date: Mineral oil Exp 03 /07/2000 Benzo IS Exp 2018 10N KOH Exp 03/26/2021 Hexane Exp 3/13/2022 Chloroform, acetic acid, ACN-MPA all Expired 2020, 2022 and 2023. 2. The TP affirmed on 7/11/2024 at approximately 4:45 p.m. the storage and possible use of reagents listed on #1 beyond its expiration date. 3. Based on the laboratory's submitted testing declaration test volume, the laboratory tests and reports approximately 1,427,236 toxicology tests samples where expired reagent may have been used.
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 surveyor's review of the laboratory's policy and procedure, six (6) randomly chosen patient records and interviews with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to perform and document preventive maintenance (PM) and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for equipment used in the laboratory for sample testing. The findings included: 1. At the time of survey, based on the surveyors' observation during the laboratory tour, review of records and documentation at approximately 5:00 p.m. on July 11, 2024, it was determined that the laboratory failed to record any PM and calibration performed on the following equipment: Urine Clinitek 500 by Siemens, Eppendorf and multichannel pipettes (Serial #s 4293163, 0400800, 44258000, 0300800 Gene Mate, 792740139 VWR, Mult pipettors, 3500700015, 36337209, 742740113) used in throughout the laboratory, timers used for RPR- syphilis serology, and fume safety hoods used for the toxicology testing. 2. The TP affirmed on July 11, 2024, at approximately 5:30 p.m. that maintenance and calibration was missed for the equipment mentioned in #1. 3. According to the laboratory's testing declaration submitted by the laboratory on July 11, 2024, the laboratory performed approximately 47,820 syphilis serology, 7,196 urinalysis, and 1,722,143 toxicology samples annually for which accuracy of results cannot be affirmed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

	which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Levy-Jennings graphs and interviews with the laboratory's testing personnel (TP) and technical supervisor (TS) on 07/11/2024 at 4: 30 p.m., the laboratory failed to document corrective action for the systematic error of quality control. The findings include: 1. On Jan 2024 there was a shift in the Levy-Jennings' graphs for WBC and RBC. The laboratory did not document corrective action over time for accuracy of quality controls test performance of the hematology analyzer. 2. The TS and TP confirmed no documentation of corrective action taken for the Levy-Jennings' shift during the month of January 2024. 3. The laboratory annual test volume for hematology reported and signed by the director on 7/9/2024 is 123,255 tests.
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 surveyors' observation during the lab tour, review of policies and procedures, six (6) randomly selected patients' test results (toxicology, hematology, routine chemistry, syphilis serology, and diagnostic immunology) and interviews with the laboratory 's office manager, technical supervisor and testing personnel on July 11, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3003, D5415, D5417, D5429, D5781, D6116, D6168 and D6170.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: The laboratory director is cited herein for failing to ensure all proficiency testing (PT) reports received identify any problems that require corrective action, such as review of quality control, calibration, and preventive maintenance records on the day the testing was performed. Findings include: 1. The laboratory received a score of 0% the following analytes by the AAB-American Laboratory Evaluation (AAB) for Urine

	Drug Screen (UDS) the third event in 2023 (M3-2023): cocaine metabolite, methadone, opiates (Morphine Trihydrate), and benzodiazepines. 2. No corrective action documentation to identify any problems on the unsatisfactory analytes AAB reported was found at the time of the survey on June 11, 2024. 3. The testing personnel confirmed by interview the lack of corrective action documentation for AAB PT report for the event listed in #1.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and completed Form CMS-209, Laboratory Personnel Report, and interview with the technical supervisor (TS) and testing personnel (TP); the laboratory director failed to employ enough laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, accurately perform tests, and report test results in accordance with the personnel responsibilities. The findings include See D6170 and D6171.
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on the deficiency cited (See D2000), the laboratory technical supervisor is herein cited for deficient practice to ensure the laboratory is enrolled in proficiency testing for all the analytes patients samples are tested and results reported.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing, Testing Personnel was not met. It was the practice of the laboratory to perform Syphilis Serology, General Immunology, and Toxicology tests on patient specimens who lack the testing qualifications requirements. see D 6170 and D6171).
D6170	TESTING PERSONNEL QUALIFICATIONS

	CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on interviews with the laboratory's technical consultant (TS) and review of testing personnel (TP) qualification records on July 11, 2024, at approximately 1:00 p. m.., the laboratory's TP failed to meet qualification requirements for conducting and reporting diagnostic tests. Findings included: 1. According to the Form CMS-209 submitted "Laboratory Personnel Report (CLIA)," signed and dated by the laboratory director on July 9, 2024, the laboratory has only one testing person performing high complexity testing without a current Clinical Laboratory Scientist license issued by the State of California. 2. The TS during an interview approximately 12:00 noon on July 11, 2024, confirmed statement #1. 3. According to the laboratory's annual volume declaration, the laboratory performed 2,081,125 tests for which the quality and accuracy of the patients' test results rendered by the laboratory cannot be assured.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for

	proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of submitted testing personnel (TP) compliancy records, review of the Laboratory Personnel Report (Form CMS-209) submitted on 7/11/2024, and lack of additional records, testing personnel credentials, and licenses on 7/11/2024; it was determined that the individuals who routinely conducted high complexity testing was not qualified to perform, review, and report high complexity test results under 493.1489(b)(2)(i). The findings included: 1. On 7/11/2024 (survey date) the laboratory was unable to provide any additional qualification records to show that the testing personnel was qualified to perform high complexity testing (Syphilis Serology, Diagnostic Immunology, and Toxicology) 2. The testing personnel affirmed on 7/11/2024 that they did not possess a Clinical Laboratory Scientist (CLS) or Medical Technologist license. 3. Based on the laboratory testing declaration (LAB 144A) signed by the laboratory director on 7/9/2024, the laboratory allowed non-qualified testing personnel to perform, review and report (Syphilis Serology, Diagnostic Immunology and Toxicology) approximately 1,711,143 high complexity tests annually.