Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0882397	05/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ca Dph Environmental Health Laboratory	850 Marina Bay Pkwy Ste G365, Richmond, 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
D0000	A recertification survey was conducted 05/12/2025 through 05/13/2025. Standard level deficiencies were cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (CLIA) form Centers for Medicare & Medicaid Services-209(CMS-209), College of American Pathologists Proficiency Testing (CAP PT), and interview with testing person-1 (TP-1), the laboratory failed to ensure blood lead proficiency testing samples were analyzed by personnel who routinely perform blood lead testing for four of four PT events. Findings included: 1. Review of the laboratory's Form CMS-209 (signed by the laboratory director 05/13/2025) listed two testing persons who routinely perform blood lead testing. 2. Review of CAP PT Blood Lead Survey attestation statement forms in 2024 (3 events) and 2025 (1 event) included TP-1's signature for analyzing four PT events. 3. During an interview on 05/12/2025 at 12:12 PM, TP-1 confirmed the PT events reviewed above were performed by by one of two TPs for submission and grading.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 review of the laboratory's written procedure, direct observation, and interview with TP-1, the laboratory failed to follow their blood lead testing procedures for storing 44 of 44 quality control (QC) vials (random sampling observed). Findings included: 1. Review of the laboratory written procedure for blood lead testing (SOP /Rev. No: 132/R4, revised date 03/27/2024) stated, "12.5. Internal quality control materials ...12.5.3. Each pool of the reference material is aliquoted into 50 mL conical tubes with ~40 mL each, and stored at -20 C. They are stable for at least three years and are analyzed in the same manner as urine specimens ...." 2. During a tour of the laboratory on 05/13/2025 at 10:38 AM, the medium and low levels of quality control material were observed stored in a -80 C freezer ("Freezer #2"), as follows: a. One box of small cryogenic specimen containers with "Blood QCC Low" (low QC level) and "Blood QCM" (medium QC level), a total of 43. b. A rack of 50 mL conical tubes, a sample included a tube labeled "Blood Reference Material LIMS: E_BMI_QCL Blood Batch: 11142011 Vial #13." The QC in cryogenic specimen containers were aliquoted from the 50 mL conical tubes for one-time use (low and medium quality control levels were prepared 11/14/2011). The laboratory did not follow their procedure for storing QC material at -20C. 3. During an interview on 05 /13/2025 at 10:38 AM, TP-1 stated QC was moved from -20 C to a -80 C freezer. The laboratory was unable to provide establishment studies to support this new storage temperature and stability for QC used in a laboratory developed test (blood lead). Refer to D5423. Word Key: SOP - standard operating procedure Rev. - revision No. - number mL - milliliters LIMS - laboratory information management system
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the laboratory's written procedure, direct observation, and interview with TP-1, the laboratory failed to monitor and document the temperature for one of one refrigerator where solutions for blood lead testing were stored. Findings included: 1. Review of the laboratory written procedure for blood lead testing (SOP /Rev. No: 132/R4, revised date 03/27/2024) stated, "7. Preparation of Reagents and Calibration Standards 7.1 Basic sample diluent ...7.1.6. Make the final volume to 2 L with 18.2 megaohm-centimeter water. The solution is stable for 3 months when stored at 4 C ..." Components for the sample diluent included, "n-Butanol (BuOH) 3.5%, NH4OH 1%, Triton X-100 0.005%, H4EDTA 0.080%, Ga, Ge, Rh, Re, Ir, Bi, DI Water." 2. Further review stated, "7.2 Basic standard diluent with synthetic matrix ... used for preparation of intermediate calibration standards ...7.2.2. Transfer the purified sodium chloride solution to 500 mL Teflon container and add the remaining

	synthetic matrix components listed in Table 3. The solution is stable for 3 months when stored at 4 C. Table 3. Preparation of the basic standard diluent with synthetic matrix ...NH4OH 2.0%, H4EDTA 0.20%, NaCl 0.80%, DI Water." A temperature range was not defined for the storage of the two prepared diluents. 3. During a tour of the laboratory on 05/13/2025 at 10:34 AM, an "Upstreman" refrigerator was observed and used to store blood lead solutions, as follows: a. One bottle labeled as, "BuOH 3.5%, NH4OH 1%, Triton 0.005%, EDTA 0.08% AU 1ppm, Ga 10ppb, Rh, Re. IR 1 ppb, Bi 4 ppb, Ge 12 ppb, 2/14/25 (TP-1 initials)" (basic sample diluent) b. One bottle labeled as, "Basic SM, NH4OH 2%, EDTA, Au 1 ppm, 2/13/2025" (basic standard diluent with synthetic matrix) 4. During an interview on 05/13/2025 at 10:34 AM, records of the refrigerator temperature were requested, TP-1 confirmed the temperature was not monitored and documented. He stated the refrigerator was put in-use "about a year ago." Word Key: NH4OH - ammonium hydroxide H4EDTA/EDTA - ethylenediaminetetraacetic acid Ga - gallium Ge - germanium Rh - rhodium Re - rhenium Ir - iridium Bi - bismuth DI Water - deionized water NaCl - sodium chloride ppm - parts per million ppb - parts per billion SM - sythetic matrix
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure and direct observation, the laboratory failed to label 44 of 44 vials of prepared blood lead quality control material (low and medium) with expiration dates as defined in their written procedure. Findings included: 1. Review of the laboratory written procedure for blood lead testing (SOP /Rev. No: 132/R4, revised date 03/27/2024) stated, "12.5. Internal quality control materials ...12.5.3. Each pool of the reference material is aliquoted into 50 mL conical tubes with ~40 mL each, and stored at -20 C. They are stable for at least three years and are analyzed in the same manner as urine specimens ...." and "12.5.10 ...The original expiration date may be extended as long as a revised mean value is within +/- 30% of the previous mean value. Otherwise, the internal QC material should be discarded and freshly prepared." 2. During a tour of the laboratory on 05/13/2025 at 10:38 AM, the medium and low levels of quality control material were observed stored in a -80C freezer ("Freezer #2"), as follows: a. One box of small cryogenic specimen containers with "Blood QCC Low" and "Blood QCM", a total of 43. b. A rack of 50 mL conical tubes, a sample included a tube labeled "Blood Reference Material LIMS: E_BMI_QCL Blood Batch: 11142011 Vial #13." The QC in cryogenic specimen containers were aliquoted from the 50 mL conical tubes for one-time use (quality control was prepared 11/14/2011). 3. The laboratory did not label the QC with expiration dates (11/14/2014) and did not have documentation of extending the expiration date 11 more years based on +/- 30% of the original mean in 2011. The laboratory had not established stability when QC material was moved from -20 C to -80 C freezer. Refer to D5423.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	(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 review of the laboratory's procedure, direct observation, and interview with TP-1, the laboratory failed to ensure 44 of 44 vials of prepared blood lead quality control material (low and medium) were not available for use. Findings included: 1. Review of the laboratory written procedure for blood lead testing (SOP/Rev. No: 132 /R4, revised date 03/27/2024) stated, "12.5. Internal quality control materials ...12.5.3. Each pool of the reference material is aliquoted into 50 mL conical tubes with ~40 mL each, and stored at -20 C. They are stable for at least three years and are analyzed in the same manner as urine specimens ...." and "12.5.10 ...The original expiration date may be extended as long as a revised mean value is within +/-30% of the previous mean value. Otherwise, the internal QC material should be discarded and freshly prepared." 2. During a tour of the laboratory on 05/13/2025 at 10:38 AM, expired medium and low levels of quality control material were observed stored in a -80C freezer ("Freezer #2"), as follows: a. One box of small cryogenic specimen containers with "Blood QCC Low" and "Blood QCM", a total of 43. b. A rack of 50 mL conical tubes, a sample included a tube labeled "Blood Reference Material LIMS: E_BMI_QCL Blood Batch: 11142011 Vial #13." The QC in cryogenic specimen containers were aliquoted from the 50 mL conical tubes for one-time use (quality control was prepared 11/14/2011). 3. According to the laboratory's procedure, prepared QC material expiration date is "at least three years" or "may be extended as long as a revised mean value is within +/-30% of the previous mean value." The QC material expired 11/14/2014 and there was no documentation to support the QC material was stable for 11 additional years with a +/-30% acceptability of the original mean value from 2011. In addition, the laboratory had not established stability when QC material was moved from -20C to -80C freezer. Refer to D5423. 4. During an interview on 05/13/2025 at 10:38 AM, TP-1 had not prepared new QC material and used the vials from the above freezer.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on interview with testing person-1 (TP-1) and review of the laboratory's written procedures, the laboratory failed to establish the performance specifications for one of one Agilent 8900 inductively coupled plasma mass spectrometry (ICP-MS) analyzer

	when installed 07/31/2023 for blood lead testing and for stability of their QC material. Findings included: 1. During an interview on 05/12/2025 at 9:45 AM, testing person-1 and the technical supervisor confirmed that there was a change of instrumentation in 2023. An Agilent 8900 analyzer had replaced their previous instrumentation and was installed 07/31/2023. 2. Review of the laboratory's written procedures did not include conducting studies on new instrumentation. 3. During an interview on 05/12/2025 at 9: 45 AM, testing person-1 stated quality control and calibration was analyzed. The laboratory did not provide documentation of verifying their existing test method on a new analyzer for blood lead testing that was reviewed and approved by the laboratory director. Refer to D6086. 4. Review of the laboratory written procedure for blood lead testing (SOP/Rev. No: 132/R4, revised date 03/27/2024) stated, "12.5. Internal quality control materials ...12.5.3. Each pool of the reference material is aliquoted into 50 mL conical tubes with ~40 mL each, and stored at -20 C. They are stable for at least three years and are analyzed in the same manner as urine specimens ...." 5. During a tour of the laboratory on 05/13/2025 at 10:38 AM, the medium and low levels of quality control material were observed stored in a -80 C freezer ("Freezer #2"), as follows: a. One box of small cryogenic specimen containers with "Blood QCC Low" and "Blood QCM", a total of 43. b. A rack of 50 mL conical tubes, a sample included a tube labeled "Blood Reference Material LIMS: E_BMI_QCL Blood Batch: 11142011 Vial #13." The QC in cryogenic specimen containers were aliquoted from the 50 mL conical tubes for one-time use (quality control was prepared 11/14/2011). 6. During an interview on 05/13/2025 at 10:38 AM, TP-1 stated QC was moved from -20 C to a -80 C freezer. The laboratory was unable to provide establishment studies to support this new storage temperature and stability for QC used in a laboratory developed test (blood lead).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedures and in interview with TP-1, the laboratory director failed to ensure studies were conducted, reviewed and approved for one of one Agilent 8900 analyzer (installed 07/31/2023). Findings included: 1. The laboratory's written procedures did not include conducting studies on new instrumentation. 2. During an interview on 05/12/2025 at 9:45 AM, testing person-1 stated quality control and calibration was analyzed. 3. The laboratory was not able to provide documentation of verifying their existing test method on a new analyzer for blood lead testing. Refer to D5423. The laboratory director did not ensure that the Agilent 8900 analyzer studies were conducted, reviewed and approved.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) 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 CAP PT, CMS-209 form, and interview with the technical supervisor, the laboratory director failed to ensure blood lead CAP PT review was delegated to an individual listed on the CMS-209 form (four of four PT events reviewed). Findings included: 1. Review of CAP PT Blood Lead Survey attestation statement forms in 2024 (3 events) and 2025 (1 event) included the Biochemistry Section Chief's signature under "Director (or Designee) (signature required)" and "Reviewed By" for PT results. 2. Review of the CMS-209 form (signed by the laboratory director 05/13/2025) did not list the Section Chief in a designated CLIA high complexity role. 3. During an interview on 05/13/2025 at 9:30 AM, the technical supervisor confirmed the laboratory director delegated PT review duties to the Biochemistry Section Chief in writing. The Biochemistry Section Chief did not have a California licensure; therefore, could not be listed as a technical supervisor. The laboratory director failed to delegate CLIA responsibilities to a qualified individual, as outlined in CFR 493.1449.