Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0882397	11/16/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory policy manual and the laboratory testing personnel competency reviews on November 16, 2018 the laboratory failed to follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings include: a. The laboratory policy on performing training and competency assessments states that the laboratory would perform and document initial training and competency assessment of all new testing staff s followed by a semi-annual competency and annually competency thereafter. b. The laboratory hired one new testing personnel during the recertification survey review years of 2017-2018. c. The laboratory failed to follow its policy and procedure's regarding performing a semi-annual competency on the new testing personnel in the first year of hire. d. The laboratory technical supervisor confirmed by interview on November 16, 2018 at approximately 11:45 am, the failure to perform and document the semi-annual competency of the new testing personnel. e. The laboratory reports performing approximately 1000 high complexity lead specimens annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel records, review of the laboratories policy and procedures, and the laboratory training and competency records on November 16, 2018, the laboratory director failed to ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings Include: a. Review of personnel competency records and review of the laboratory policy and procedure manual revealed that the laboratory did not have a policy or procedure for evaluating the competency of the individuals identified on the CMS-209 as the technical supervisor, clinical consultant or the general supervisor. b. The laboratory did not have documentation of competency for technical supervisor, the clinical consultant or the general supervisor for the survey review years of 2016, 2017, or 2018. c. The laboratory technical supervisor confirmed this lack of policy by interview on November 16, 2018 at approximately 1:00 pm. d. The laboratory reports performing 1000 high complexity lead testing annually.
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 personnel policy manual, staff competency records on November 16, 2018, the laboratory director failed to specify, in writing, the responsibilities and duties of 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. Finding Includes: a. The laboratory has a multi-layered process for review for patient testing results prior to releasing of reports to the requestor. Review of patient testing flows through unlicensed testing personnel, unlicensed personnel, to the general supervisor, and then to technical supervisor. b. Upon review of the laboratory staff training and competency records, the laboratory has no documentation regarding the extent of the responsibilities and duties of the laboratory technical supervisor, the general supervisor, the licensed testing personnel, and unlicensed personnel who are engaged in preanalytic, analytic and postanalytic phases of patient testing, regarding delegated duties, responsibilites and testing approval authorized by the laboratory director. c. The laboratory technical supervisor,

	general supervisor confirmed by interview on November 16, 2018 at approximately 12:30 pm the lack of documentation regarding the roles, responsibilities and authorization for staff engaged in patient testing. d. The laboratory reports performing 1000 high complexity lead tests annually.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the personnel training and competency records on November 16, 2018, the technical supervisor failed to evaluate and document the performance of new individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings Include: a. The laboratory hired one new testing personnel (#6 on CMS-209) on November 2016, the initial training of the testing personnel was signed off on January 9, 2017. b. The next competency for testing personnel (TP) #6, was performed on April 23, 2018. c. The laboratory did not perform a semiannual competency during the first year of testing on TP #6. See D tag 5209 d. The omission of the semiiannual competency was confirmed by interview by the laboratory Technical Supervisor on November 16, 2018 at approximately 11:00 am. e. The laboratory reports performing 1000 high complexity lead tests annually.
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 review of the laboratory personnel licensing and education transcripts, the laboratory failed to ensure that each individual performing high complexity testing possess a current license issued by the State in which the laboratory is located, if such licensing is required. Findings Include: a. The laboratory is a public Health Laboratory for California. California has testing personnel licensing requirements. b. Two of two CMS-209 identified testing personnel lack state licensure for Toxicology testing in accordance to CA BPC 1206.5 (c)(3). and CMS 42 CFR 493.1461(a). c. The laboratory technical supervisor confirmed by interview on November 16, 2018 at approximately 11:00 am, that the two testing personnel did not have the required state licensure. d. The laboratory reports performing approximately 1000 high complexity Lead specimens annually.