

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0882397	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier Ca Dph Environmental Health Laboratory	Street Address, City, State 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel competency assessment records, review of laboratory procedures, and interview with laboratory personnel on April 18, 2023, the laboratory failed to follow its written procedures to assess employee competency. a. According to laboratory procedure, "Analyst Training and Competency," continuing competency will be documented on the 'Continuing Competency Form.' b. At the time of the survey on April 18, 2023, the laboratory maintained no documentation to indicate that competency of testing personnel (TP#2) at least semiannually during the first year of patient testing had been assessed in 2022. c. The technical supervisor confirmed on April 18, 2023 at 11.21 a.m. the failure to follow written procedures to document testing personnel competency assessment at least semiannually during the first year of patient testing. See D6127</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation, review of laboratory procedures, and interview with laboratory personnel on April 18, 2023, the laboratory failed to follow its procedure to perform annual analytical balance calibration. Findings included: a. During a tour of the laboratory on April 18, 2023, Mettler Toledo analytical balance, S/N: B109116570, past due calibration service, January 2023, was observed. b. According to laboratory procedure, 'Equipment Calibration and Maintenance,' analytical balances are to be calibrated annually. At the time of the survey on April 18, 2023, the laboratory maintained no documentation to indicate that the annual calibration of the Mettler Toledo analytical balance had been performed. c. Based on interviews with laboratory personnel, it is the practice of the laboratory to perform calibration checks of pipettes used in patient testing using the Mettler Toledo analytical balance. d. The laboratory director and testing personnel confirmed on April 18, 2023 at 9.39 a.m. that the annual calibration of the analytical balance had not been performed.

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 laboratory testing personnel training and competency records, and interview with laboratory personnel on April 18, 2023, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity patient testing at least semiannually during the first year of patient testing. Findings include: a. Evaluations of testing personnel (TP#2) competency for performing patient testing were documented initially in 2022 during the first year of patient testing, and annually in 2023. b. At the time of the survey on April 18, 2023, the laboratory maintained no documentation to indicate that competency of testing personnel (TP#2) at least semiannually during the first year of patient testing had been assessed by the technical supervisor in 2022. c. The technical supervisor confirmed on April 18, 2023 at 11.21 a.m. the failure to evaluate and document the performance of TP#2 competency at least semiannually during the first year of patient testing. See D5209