| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2112676 | 10/11/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ca Dept Of Public Health, Drinking Water & | 850 Marina Bay Pkwy, Rm G-164, 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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of the laboratory's CDC proficiency testing (PT) submission records on October 11, 2018, the laboratory director failed to attest in writing to the routine integration of the PT samples into the laboratory patient workload using the laboratory's routine methods. Findings include: 1. The laboratory receives CDC proficiency testing kits for 12 analytes three times a year. For the years 2017 and 2018 the laboratory testing personnel and the general supervisor are the only signatures on five out of five PT testing records. a. Event 01-2017 d. Event 01-2018 b. Event 02-2017 e. Event 02-2018 c. Event 03-2017 2. Although the testing personnel and the general supervisor signed the attestation for the integration of PT samples into the routine workload, the general supervisor does not have documented delegated authority to perform this responsibility for the laboratory director. 3. The laboratory director, technical supervisor and general supervisor confirmed by interview the lack of designation/delegation of authority to the laboratory general supervisor on October 11, 2018 at approximately 10:00 am. 4. The laboratory reports performing 100 tests per year. |
| **D6107** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(15)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on personnel record review and training and competency records on October 11, 2018, the laboratory director failed to 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. Findings include: 1. The laboratory lists four testing personnel on the CMS-209. The laboratory utilizes the general supervisor and two additional staff (A), (B) as subject matter experts (SME) to perform portions of the testing personnel's direct observation and monitoring of testing performance during annual competency and training processes. 2. The annual competency and training records for 4 out of four testing personnel do not identify the level of performance each individual is authorized to perform or if the individuals requires supervisory or director review prior to reporting patient test results. 3. The laboratory director failed to specify in writing the responsibilities and duties of the technical supervisor or general supervisor. See D tag 2009. 4. The testing personnel identified as SME's (A), (B), do not have documentation indicating they have the authority to perfom as SME's by the laboratory director. 5. The laboratory director, by interview on October 11, 2018 at approximately 10:00 am, confirmed the lack of written authorization for the technical supervisor, general supervisor, subject matter experts or testing personnel, specifying the level of performance each individual are authorized to perform. 6. The laboratory reports performing approximately 100 specimens annually. |
| **D6128** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of testing personnel training and annual competency records on October 11,2018, the laboratory director/ technical supervisor failed to delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and annually evaluating and documenting the performance of all testing personnel. Findings include: 1. According to the CMS-209 submitted by the laboratory on the day of survey, the laboratory listed four testing personnel. Two testing personnel had been hired during the survey review years 2017(C) and 2018 (D). a. The general supervisor had conducted and signed off the training and midyear reviews of the new staff (C), (D). b. The general supervisor had conducted and signed off the annual competency for staff (C) and the midyear and annual competency for testing personnel (D). 2. The laboratory general supervisor did not have a letter of |

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| | delegation of authority for approving training and annual competency for testing personnel. 3. The laboratory director and/or technical supervisor failed to document approval of testing personnel initial training, semi-annual and annual competency records of the new testing personnel (C), (D) and the annual competency of the testing personnel (A), (B) indicating what level of competecny each were approved for testing, reporting laboratory specimens specimens. see D tag 6107. 4. The laboratory director, the technical supervisor and the general supervisor confirmed by interview on October 11, 2018 at approximately 10:00 am, that the general supervisor did not have a delegation of authority for the general supervisor to perform the responsibilities of the laboratory director or Technical Supervisor in accordance to 42 CFR 493.1445(a)((e)(4)(15). 5. The laboratory reports performing approximately 100 specimens annually. |