

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0711439	(X3) Date Survey Completed 07/10/2018
Name of Provider or Supplier Madera County Public Health Laboratory	Street Address, City, State 1604 Sunrise Ave, Madera, 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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review and the lack of documentation of Quality Control (QC) performance for Oxidase, Catalase, and interview with the laboratory director, it was determined that the laboratory failed for each qualitative procedure, include a negative and positive control materials; the laboratory must document all control procedures performed. The findings included: a. The laboratory lack the documentation and performances at least once day patients specimens are assayed or examined perform include negative and positive control materials for Oxidase, and Catalase, tests. b. For one (1) out of one (1) random patient sampling result reviewed (3/8/2018); the laboratory analyzed and reported a Bacteriology test without performing an Oxidase, and a Catalase tests. c. The laboratory director affirmed (7/10/2018, 12:30) that the laboratory did not include negative and positive control materials for the above tests.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs</p>

are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review and the lack of documentation of the laboratory's quality control (QC) performance, and the competency evaluation for all testing personnel, it was determined that the laboratory director/technical consultant/and or technical supervisor failed to ensure the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. See D5449, D6053, and D6127.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on request, review and the lack of documentation for competency assessments, and interview with laboratory director, for nine (9) out of nine (9) random patient sampling test results reviewed covering period from 6/16/2016 to 5/25/2018, it was determined that the laboratory technical consultant/laboratory director failed to perform and document the performance of individuals responsible for moderate complexity testing. The findings included: a. There was no documentation to show that the testing personnel were evaluated during the first six months and annually thereafter. The evaluations must include but are not limited to the following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. There are two (2) testing personnel (TP) listed on the CMS 209 and LAB 116 forms, no documentation of competency and evaluation for the years 2016, 2017, and 2018. c. The laboratory director affirmed (7/10/2018, 12:30) that no competency assessments were performed and documented by the laboratory director and or technical consultant.

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 request, review and the lack of documentation for competency assessments, and interview with laboratory director, for nine (9) out of nine (9) random patient sampling test results reviewed covering period from 6/16/2016 to 5/25/2018, it was determined that the laboratory technical supervisor/laboratory director failed to perform and document the performance of individuals responsible for high complexity testing. The findings included: a. There was no documentation to show that the testing

personnel were evaluated during the first six months and annually thereafter. The evaluations must include but are not limited to the following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. There are two (2) testing personnel (TP) listed on the CMS 209 and LAB 116 forms, no documentation of competency and evaluation for the years 2016, 2017, and 2018. c. The laboratory director affirmed (7/10/2018, 12:30) that no competency assessments were performed and documented by the laboratory director and or technical supervisor.