

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0644025	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier Merced County Public Health Laboratory	Street Address, City, State 260 E 15th St, Merced, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor's review of quality control (QC) testing records for the Xpert MTB /RIF Assay performed on the GeneXpert Instrument Systems for the detection of Mycobacterium tuberculosis complex DNA in sputum, patients test records, and interview with the laboratory general supervisor, the laboratory failed to perform QC each day of patient testing or to establish an IQCP (Individual Quantity Control Plan). The findings include: a. Laboratory QC testing records could not be retrieved to showed that the laboratory performed QC for each day of patient testing or established an IQCP. The Xpert MTB/RIF assay user's manual under "External Controls" stated: External controls should be used in accordance with local, state, and federal accrediting organizations' requirement as applicable. Date PT ID Xpert MTB/RIF Assay 08/13/19 MC19-00956 Neg 08/13/19 MC19-00958 Neg b. On 10/24/2019 12:00 pm laboratory general supervisor confirmed that the laboratory did not run QC everyday of patient testing or established an IQCP. c. The laboratory Technical Supervisor testing stated that the laboratory performs 2 tests annually.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of patients reports, lack of daily in-use quality control (QC) control documents, and interview with general superior, it was determined that the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided (See 5445).

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 and the lack of documentation for competency assessments, and interview with the general supervisor, it was determined that the laboratory technical supervisor failed to perform and document the performance of individuals responsible for high complexity testing. The evaluations must include but are not limited to the following: a. No semiannual performance evaluation documentation of could be retrieved for the new testing personnel evaluated during the 2019 period. The laboratory's quality assessment manual section Title "XII. Personnel Competency Assessment Policy" under Policy stated: Competency assessment shall be performed annually for all public health microbiologists. Newly hired public microbiologists should be assessed twice during the first year of testing and annually thereafter. The section microbiologists are responsible for assessing testing personnel in the section. The Laboratory director or Designee shall conduct assessment of the microbiologist. 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. The laboratory general supervisor confirmed on 10/24/2019 12:00 pm (survey day) that no semiannual competency assessments (during the first year an individual tests patient specimens) was performed and documented by the laboratory director and technical supervisor. c. Based on the laboratory's annual testing declaration submitted for 2019, the laboratory analyzed and reported approximately 437 high complexity tests.