

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2146683	(X3) Date Survey Completed 07/11/2019
Name of Provider or Supplier Sutter Gould Medical Foundation	Street Address, City, State 445 W Eaton Ave, Ste 1121, Tracy, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation on the day of the survey (7/11/2019) there were fifteen (15) Blue top tubes (3.2 Na Citrate) Lot # 9002613, expiration date 6/30/2019 found, and interview with the laboratory personnel, it was determined that the laboratory had used test tubes that exceeded their expiration date. The findings included: a. Based on direct observation, on the day of the survey (7/11/2019) there were fifteen (15) Blue top tubes (3.2 Na Citrate) test tubes found in the laboratory drawer that indicated its being used or have the potential of being used even though the expiration dates had exceeded. b. The laboratory personnel confirmed (7/11/2019, 1230) that the laboratory had expired test tubes inside the laboratory's drawer; (15) Blue top tubes (3.2 Na Citrate) that had exceeded their expiration dates.</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 are established and maintained to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:
Based on review and the lack of documentation for competency assessment and interview with the laboratory personnel, it was determined that the laboratory failed to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. See D 5417 and D 6053

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 review and the lack of documentation for competency assessments and interview with the laboratory personnel, for six (6) out of six (6) random patient test records reviewed covering period from 7/4/2018 to 5/16/2019, it was determined that the Laboratory Director/Technical Consultant failed to perform and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The evaluations must include but are not limited to the following: The findings included: a. There was no documentation to show that the testing personnel for twelve (12) out of twelve (12) were evaluated during the first six months and annually thereafter for Hematology. The evaluation must include 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. The laboratory personnel confirmed (7/11/2019, 1230) that no competency assessments were performed and documented by the Laboratory Director/Technical Consultant.