

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2007262	(X3) Date Survey Completed 03/05/2019
Name of Provider or Supplier Sutter Gould Medical Foundation Lab	Street Address, City, State 2505 W Hammer Lane, Stockton, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Siemens Dimension Xpand chemistry analyzer and a Microscope, review of laboratory reports for Wet Mount, KOH, and CRP (C-Reactive Protein), the lack of laboratory documents, and interview with laboratory personnel, it was determined that the laboratory failed to verify the accuracy of testing at least twice a year. Findings included: a. The Dimension Xpand provided results for CRP. Testing persons microscopically determined the presence or absence of Yeast, Trichomonas, WBC (White Blood Cells), and Clue cells in Wet Mounts and fungal hyphae in KOH. b. For 4 out of 4 laboratory reports randomly selected from 2017 - 2019 for CRP and 10 out of 10 reports for vaginal Wet Mounts, the laboratory failed to provide a policy and records for verifying the accuracy of testing at least twice annually. c. A laboratory person affirmed (3/05/19 at 5:30pm) the aforementioned lack of laboratory records; and thus the laboratory's failure to have a policy, procedures, and records for at least twice annually verifying the accuracy of testing for CRP, Wet Mounts, and KOH. d. The reliability and quality of results reported for CRP, Wet Mount, and KOH could not be assured in the absence of verifying the accuracy of testing at least twice annually. Based on the stated test volumes, the laboratory reported approximately 2 KOH, 152 Wet Mounts and 2,130 CRP annually.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based on observation of the Siemens Dimension Xpand chemistry analyzer, review of laboratory records verifying test calibrations, the lack of documents, and interview with laboratory personnel, the laboratory failed to perform calibration verification procedures at least once every 6 months in 2009 to October 2018. Findings included:
 a. The Siemens Dimension Xpand chemistry analyzer (serial number 2004082056) was in use since 2009. Electrolytes Cl (Chloride), Na (Sodium), and K (Potassium) were calibrated using Quicklyte Standard A and Standard B. b. A laboratory person affirmed (3/05/19 at 5:30pm) that the calibrations for electrolytes required verifying and provided for review laboratory records dated October 2018. The laboratory was unable to provide additional records for review. d. The laboratory person affirmed (3/05/19 at 5:30pm) the aforementioned lack of laboratory records; and thus, the laboratory's failure to verify calibrations at least once every 6 months since 2009 to October 2018. e. The reliability and quality of Cl, Na, and K results reported 6 months after initial installation in 2009 through September 2018 could not be assured when calibrations had not been verified at least once every 6 months. Based on the reported annual tests volumes for 2018, the laboratory reported approximately 90,000 results (30,088 X 3) each year since 2009. .

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the cumulative nature of deficiencies cited, the Laboratory Director is herein cited for deficient practice in providing overall administration to ensure requirements are met. Findings included: a. Under the Laboratory Director's administration the laboratory failed to have a policy, procedures, and records verifying the accuracy of testing at least twice annually for non-regulated analytes not enrolled in proficiency testing. See D5217. b. Under the Laboratory Director's administration the laboratory failed to have a policy, procedures, and records for verifying calibrations at least once every 6 months. See D5439.