

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0911779	(X3) Date Survey Completed 04/23/2019
Name of Provider or Supplier Sutter Maternity & Surgery Center	Street Address, City, State 2900 Chanticleer Ave, Santa Cruz, 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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Review of proficiency testing reports from CMS (Report 155D, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records for Event 1, 2017, and patients test records; and interview with laboratory personnel and the Technical Consultant revealed the failure to attain a score of at least 80 percent when performing point-of-care testing for pCO2 Blood Gas. Findings included: a. CMS and API reported the score of 40% based on the laboratory's 3 unacceptable results out of 5: PT sample Lab Result Acceptable ----- BG-02 60 61 - 72 BG-03 43 46 - 57 BG-05 30 37 - 48 b. Laboratory personnel and the Technical Consultant affirmed (4/23/19 at 4pm) the aforementioned score using the EPOC analyzer; and thus unsatisfactory testing for pCO2 Blood Gas. c. The reliability and quality of results reported for pCO2 Blood Gas at point of care testing for Neonates could not be assured for the timeframe January to May 2017. Examples include 4 of 4 selected at random: Date ID ----- 1/25/17.....61638151 2/18/17.....61674452 3/13 /17.....61704005 4/20/17.....61757707 . .</p>
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2)</p>

The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the proficiency testing report from API, laboratory proficiency testing records, and interview with laboratory personnel, it was determined that the laboratory failed to participate in Event 1, 2017, for Hematocrit. Findings included: a. API reported No Grading for 5 out of 5 samples based on the laboratory's failure to report results. b. Laboratory proficiency testing records revealed testing was performed on 2/23/17 after API's deadline for reporting. c. Laboratory personnel affirmed (4/23/19 at 5pm) the aforementioned findings; and thus the laboratory's failure to participate in the testing event. d. The reliability and quality of results reported could not be assured in the absence of participation in proficiency testing. Based on the stated annual test volume of 400, the laboratory reported approximately 166 Hematocrits during the timeframe January to May 2017. .

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing records for Event 2, 2017; API proficiency testing report, and patients test records; the lack of laboratory documents, and interview with laboratory personnel, it was determined that the laboratory failed to verify the accuracy of testing for ROM (Rupture of Membrane) using the Clinical Innovations ROM Plus test cartridges. Findings included: a. The laboratory chose to participate in API's proficiency testing program as the means to satisfy the requirement to at least twice annually verify the accuracy of testing for ROM. b. API reported the unsatisfactory score of 67%. c. The laboratory failed to provide for review other documents verifying the accuracy of testing during this timeframe. d. Laboratory personnel affirmed (4/23/19 at 5pm) the aforementioned score and lack of laboratory documents; and thus accuracy of testing was not verified. e. The reliability and quality of results reported for ROM could not be assured in the absence of accurate testing. Based on the stated annual test volume of 125, the laboratory reported approximately 50 results during the timeframe November 2017 to March 2018. Five reports randomly selected are as follows: Date ID -----
11/21/17G, V 12/18/17.....P, J 1/23/18.....L, C 2/21/18.....O, C 3/19/18.....T, J .

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the deficiency cited (D5217), review of 2016 - 2017 laboratory proficiency testing records for ROM, reports from API, and patients test records, the lack of laboratory documents, and interview with laboratory personnel, it was determined that the laboratory failed to review the effectiveness of previous corrective actions to prevent recurrence and correct problems identified in testing for ROM. a. The laboratory chose to participate in API's proficiency testing program for ROM; and demonstrated unsatisfactory testing in 3 out of 4 consecutive events as follows: Event Score ----- 2, 2016.....50% 3, 2016.....50% 2, 2017.....67% b. The laboratory was unable to provide for review documents assessing the effectiveness of corrective actions from 2016 to evaluate and correct problem(s) identified in Event 2, 2017. c. Laboratory personnel affirmed the aforementioned lack of quality assessment documents.