Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0911779	**(X3) Date Survey Completed** 04/28/2021
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**
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) 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) 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 a review of the proficiency testing (PT) report from API, a review of the laboratory proficiency report and an interview with the LP (laboratory personnel), it was determined that the laboratory failed to participate in the event 3, 2019 events for Chemistry. The inspection was completed on 4/28/2021 between 1:00 p.m. and 3:00 P. M. Findings include: 1. A CLIA inspection was completed on 4/28/2021 between 1:00 p.m. and 3:00 p.m. 2. The laboratory submits PT results each quarter to API for Chemistry 3. After a review of the CMS 96 report and the laboratory API report for event 3, 2019, it was determined that no proficiency scores were submitted 4. The LP reviewed the findings and affirmed the results (failure to submit resulting in a score of 0). 5. No PT results for this cycle were documented for the following (analyte/analyte number): Routine Chemistry (0245) Ph Blood Gas (0315) PO2 Blood Gas (0325) PC02 Blood Gas (0335) Glucose (0415) K (0465) NA (0475) 6. Proficiency results for Chemistry were submitted by this laboratory for Events 1 and 2 in 2019 and Events 1,2 and 3 for 2020 and Event 1 for 2021.
D2123	HEMATOLOGY

	CFR(s): 493.851(c) 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) 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 a review of the proficiency testing (PT) report from API, a review of the laboratory proficiency report and an interview with the LP (laboratory personnel), it was determined that the laboratory failed to participate in the event 3, 2019 events for Chemistry. The inspection was completed on 4/28/2021 between 1:00 p.m. and 3:00 P. M. Findings include: 1. A CLIA inspection was completed on 4/28/2021 between 1:00 p.m. and 3:00 p.m. 2. The laboratory submits PT results each quarter to API for Hematology 3. After a review of the CMS 96 report and the laboratory API report for event 3, 2019, it was determined that no proficiency scores were submitted 4. The LP reviewed the findings and affirmed the results (failure to submit resulting in a score of 0). 5. No PT results for this cycle were documented for the following (analyte/analyte number): Hematology (0760) HGB (0795) 6. Proficiency results for Hematology were submitted by this laboratory for Events 1 and 2 in 2019 and Events 1,2 and 3 for 2020 and Event 1 for 2021.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the proficiency testing (PT) report from API, a review of the laboratory proficiency report and an interview with the LP (laboratory personnel), it was determined that the laboratory failed to participate in the event 3, 2019 events for Chemistry. The inspection was completed on 4/28/2021 between 1:00 p.m. and 3:00 P. M. Findings include: 1. See Dtag 2089 and Dtag2123.