

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0911779	(X3) Date Survey Completed 03/13/2024
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of random selected patients sampling test orders and interviews with the technical consultants (TSs), it was determined that the laboratory failed to have a written or electronic request for patient testing from an authorized person. The findings included: 1. On the day of the survey March 13, 2024 for one (1) out of five (5) patients' test requisitions requested for review the laboratory had no documentation to show of a test order from an authorized person. 2. For one (1) out of five (5) random selected patients test orders reviewed covering period from 2/19/2022 to 2/13/2024, the laboratory analyzed and reported Fern test results without a written or electronic request for patient testing from an authorized person. 3. The TSs confirmed that the laboratory has no documentation to show for a written or electronic request for the above patient test results from an authorized person.</p>
D6007	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p>

This STANDARD is not met as evidenced by:
Based on observation, review of the laboratory records, and interview with the technical consultants; it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing. The findings included: See D5301 and D6054.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality assessment procedures, lack of competency assessment documents for all testing personnel (TP) and technical consultants (TCs) available for review, and interviews with the TCs; it was determined that the TCs had failed to perform and document annually the competency of the TP and other TCs as required annually. The findings included: 1. At the time of survey March 13, 2024, there were no competency evaluation documents for two (2) out of ten (10) randomly chosen test competency records. 2. No competency records were available for the year 2023 for one TP and one TC to include: 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 3. The TCs confirmed on March 13, 2024, at approximately 12:45 p.m. statement 2 above. 4. Based on the laboratory's testing declaration submitted and signed by the laboratory director March 11, 2024, there were 1,217 tests analyzed and reported without competency evaluation for all TP and TCs.