

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2009927	(X3) Date Survey Completed 02/27/2019
Name of Provider or Supplier California Center For Reproductive	Street Address, City, State 477 El Camino Real, Ste C310, Encinitas, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of the first quarter (Q1-2017) American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed to verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance. The findings included: a. Q1-2017, AAB proficiency testing, the laboratory received a 100% score for Sperm Count, traditional (Makler) analyte. Spec.: Reported Value: Grading Range: Mean: #1? 54 4-18 11.3 Note: True score for Sperm Count, Traditional (Makler) should have been 50%. Per AAB footnote (?) denotes that, " This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus. b. For eight (8) out of eight (8) random patient test results reviewed covering period from 2/1/2017 to 2/7/2019 , eight (8) patients have Sperm Count, traditional (Makler) test analyzed and reported that cannot be assured. c. The testing personnel confirmed (2/15/2019, 16:15) that the laboratory received the above artificial 100% score for Sperm Count, traditional (Makler) test analyzed and reported that cannot be assured, and that the laboratory did not have a corrective action for the failure in the proficiency testing.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the (AAB) proficiency testing records, random patient sampling test results and interview with the testing personnel, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 5215. .