

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0965523	(X3) Date Survey Completed 08/23/2022
Name of Provider or Supplier West Coast Fertility Centers, Llc	Street Address, City, State 11160 Warner Ave Ste 411, Fountain Valley, 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 review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of the semen viability and motility counts. The findings included: a. The laboratory performed sperm count in an IVF laboratory. b. The laboratory elected to enroll with AAB (American Association of Bioanalysts) PT program to verify the accuracy of the sperm motility and sperm viability. c. The laboratory obtained scores of 50 % for Motility and Viability, respectively in S1 2022 AAB PT event, which was unsatisfactory performance. d. The laboratory performs Motility and Viability counts in approximately 42 patient specimens monthly. e. The laboratory staff affirmed (8/23/2022 @ 10:05 am) that the laboratory obtained 50% for Motility and Viability counts in S1, 2022 AAB PT which was unsatisfactory performance.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and interview with the laboratory staff, it was determined that the laboratory director failed to review the</p>

procedures and approve, sign and date it. The findings included: a . There was no current laboratory director's signature on the laboratory's procedure manual