

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0883369	(X3) Date Survey Completed 03/07/2018
Name of Provider or Supplier Fertility Center Of California	Street Address, City, State 12791 Newport Ave Ste 206, Tustin, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory written policies and procedures, and interview with the laboratory staff, it was determined that the laboratory failed to have a proper written policies and procedures on site. The findings included: a. At the time of the survey (3/7/18), the laboratory did not have a written procedure manual on site with correct laboratory address, to indicate where the laboratory operated. b. The laboratory staff affirmed (3/7/18 @ 11:35 am) that the written policies and procedure at hand had different laboratory address.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory patient test result reports, and interview with the laboratory staff, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings</p>

included; a. The laboratory performed complete semen analyses (CSA) for its patients. b. One of the two patient CSA test results reports were reviewed and one of these reports, ID #35617 performed on 03/03/2018, found to have patient first name transcribed incorrectly. c. The laboratory staff affirmed (3/7/18 @11:05 am) that the first name of the patient full was incorrectly transcribed. d. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory patient test results reports and records, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: See D-5401 and D-5891