

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1006210	(X3) Date Survey Completed 06/25/2019
Name of Provider or Supplier Fertility Center Of California	Street Address, City, State 6699 Alvarado Rd, Ste 2207, San Diego, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory written procedure for performing Semen Analysis, patients test records, and manufacturers' product information; lack of laboratory documents, and interview with Testing Person-1, it was determined that the laboratory failed to have a system that twice a year compared test results from different methods for measuring specimen volume and different counting chambers. Findings included: a. The laboratory procedure for Semen Analysis, in effect 5/07/12, stated different acceptable methods for measuring specimen volume and use of different counting chambers: 1) Volume i. Measure volume with a volumetric pipette ii. Measure volume with a digital scale 2) Counting chamber: i. Use a Makler counting chamber ii. Use a MicroCell counting chamber b. The laboratory was unable to provide for review written policy and procedure and records for a system that twice a year compared Semen Analysis results by the different methods of measuring volume and different counting chambers. c. Manufacturers stated their product information as follows: 1) Makler chamber: Re-usable; Depth of 10 microns 2) MicroCell chamber: Single use; Depth of 20 microns d. Testing Person-1 affirmed (6/25/19 at 1pm) the use of all aforementioned methods and lack of policy and procedures for comparing test results twice each year. e. Ten out of 10 patients test records randomly selected from 11/2017 - 4/2019 failed to identify which methods were used to perform the analyses. Based on the stated estimated annual test volume, the laboratory reported approximately fewer than 400 Semen Analyses each year. f. The reliability, reproducibility, and</p>

quality of Semen Analysis results could not be assured in the absence of documented activities comparing different methods twice each year..

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on the deficiency cited (D5445), and review of the Personnel Report, the Laboratory Director is herein cited for deficient practice in providing scientific oversight as Technical Supervisor. Findings included: a. The Laboratory Personnel Report (CLIA) [form CMS-209, 6/05/19] stated the Laboratory Director held the responsibilities as Technical Supervisor to provide scientific oversight for the high complexity testing. b. As Technical Supervisor, the Laboratory Director failed to establish a system to monitor different methods of analytic performance and twice each year document comparisons in test results. c. See D5445.