

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0979897	<b>(X3) Date Survey Completed</b>  12/04/2019
<b>Name of Provider or Supplier</b>  Fertility Care Of Orange County	<b>Street Address, City, State</b>  203 N Brea Blvd Ste 100, Brea, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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 first quarter (Q1-2019) of the American Association of Bioanalysts (AAB) performance summary report for Sperm Count and interview with the TP, it was determined that the laboratory failed to 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. The findings included: a. Q1-2019, AAB reported an unsatisfactory score of 50% for Sperm Count. b. For seven (7) out of seven (7) random patient test results reviewed covering period from April 15/2019 to 10/9/2019, three (3) had Sperm count ordered, analyzed and reported which the laboratory received the unsatisfactory score of 50% for Sperm Count. c. The TP confirmed (12/4/2019, 12:30) that the laboratory received the above proficiency testing score.</p>
<b>D5401</b>	<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 and lack of laboratory written policies and procedures, and interview with the testing personnel (TP), it was determined that the laboratory failed to</p>

establish and follow written procedures for Sperm Count test. The findings included:  
a. On the day of the survey (12/4/2019, 1100) the laboratory failed to provide a written policy and procedure for Sperm Count. b. For seven (7) out of seven (7) random patient test results reviewed covering period from April 15/2019 to 10/9/2019, three (3) had Sperm count ordered, analyzed and reported which the laboratory had no policy and procedure established. c. The TP confirmed (12/4/2019, 12:30) that the laboratory lacked an established policy and procedure for Sperm Count.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review and lack of laboratory written policies and procedures, and interview with the testing personnel (TP), it was determined that the laboratory failed to establish and follow written procedures for Sperm Count (Insemination) test. The findings included: a. On the day of the survey (12/4/2019, 1100) the laboratory failed to provide a written policy and procedure for Sperm Count for (Insemination) which requires a pre Sperm count. b. For five (5) out of seven (7) random patient test results reviewed covering period from April 15/2019 to 10/9/2019, five (5) had Sperm count performed and reported which the laboratory had no policy and procedure established. c. The TP confirmed (12/4/2019, 12:30) that the laboratory lacked an established policy and procedure for Sperm Count (Insemination).

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on observation and lack of room and incubator temperature logs and interview with the TP, it was determined that the laboratory failed to monitor and document temperatures. The findings included: a. On the day of the survey, 12/4/19 based on observation and interview with TP, the laboratory failed to provide documentation for the incubator and room temperatures. b For seven (7) out of seven (7) random patient test results reviewed covering period from April 15/2019 to 10/9/2019, all were analyzed and reported without documentation and proper monitoring of the incubator and room temperatures that are essential for the testing. c. The TP confirmed on 12/4 /2019, 12:30 that the laboratory has no documentation for the incubator and room temperatures

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory quality control (QC) records, and interview with the TP, it was determined that the laboratory failed to establish its quality control procedures that monitor the accuracy and precision of the complete analytic process including the number, the type, and the frequency of the QC materials when doing Sperm Count (Insemination) test. a. On the day of the survey 12/4/2019, it was observed that QC was not performed whenever a Sperm Count (Insemination) procedure is performed. b. For five (5) out of seven (7) random patient test results reviewed covering period from April 15/2019 to 10/9/2019, five (5) had Sperm count (Insemination) ordered, analyzed and reported which the laboratory had no policy and procedure established. c. The TP confirmed (12/4/2019, 12:30) that the laboratory lacked an established policy and procedure for Sperm Count.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

The laboratory director must 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.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policy and procedure manual (See D 5401 and D 5403), lack of monitoring and documentation for incubator and room temperatures (D

5413), no documentation for QC for Sperm Count (Insemination) procedure, proficiency failure (D 5217) and interview with the TP, it was determined that the laboratory director failed 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, analytic, and postanalytic phases of testing.