

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2157169	<b>(X3) Date Survey Completed</b> 03/23/2022
<b>Name of Provider or Supplier</b> Spring Fertility	<b>Street Address, City, State</b> 80 Grand Ave Ste 300, Oakland, 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>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 Surveyor review of laboratory's procedure manual and interview with the laboratory testing person on March 23, 2022, at 2:10 pm, the laboratory testing person failed to follow the sperm count procedure. The findings include: 1. The laboratory used Makler counting chamber for the sperm count test. According to the laboratory's procedure manual the count needs to be performed in duplicate. However, the testing person #1 had been counting in singlicate and was not following the laboratory's procedure manual. Therefore, the sperm count test accuracy can not be assured. 2. The laboratory testing person on March 23, 2022, at 2:10 pm, affirmed that the sperm count test was done in singlicate. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/18/2022, stated that the laboratory performs approximately 750 sperm count tests, annually.</p>
<b>D6087</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's procedure manual and interview with the</p>

laboratory testing person on March 23, 2022, at 2:10 pm, the laboratory director failed to ensure that the laboratory personnel performed the sperm count test method as outlined in and required by the laboratory's policy. The findings include: See D5401.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's procedure manual and interview with the laboratory testing person on March 23, 2022, at 2:10 pm, the laboratory director failed to ensure that the competent personnel are performing the test. The findings include: See D5401.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's records, lack of laboratory director's assigned responsibilities to each laboratory person in writing, and interview with the laboratory testing person on March 23, 2022, at 2:30 pm, the laboratory director failed to specify in writing the responsibilities of each supervisor and person engaged in the testing. The findings include: The laboratory could not provide any written document showing that the laboratory director had assigned duties and responsibilities to the supervisors and testing personnel. The director must assign, in writing, the duties /responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.