

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0936846	<b>(X3) Date Survey Completed</b> 05/25/2018
<b>Name of Provider or Supplier</b> Pacific Reproductive Center	<b>Street Address, City, State</b> 3720 Lomita Blvd Ste 200, Torrance, 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 policy &amp; procedure, quality control data and random patient testing records, and interview with the laboratory manager and staff, the laboratory staff failed to follow the lab director's approved procedure for semen analysis. The findings include: a. The laboratory's sperm count procedure in the andrology lab manual, page 4 and 5, states that the sperm count should be repeated with another drop of the specimen to determine the average count, and the agreement limit between replicate counts should be less than 10%. However, the laboratory failed to provide any document showing that the patients' sperm specimen, Accession # 111017-902 and 032118-207, were counted by repeating with another drop of the specimen. Due to the lack of repeated analytic test records, it could not be assured that the test was repeated, and the reported test result for the above patients was accurate. b. On May 25, 2018 at 2:10 pm laboratory manager and staff affirmed that the laboratory did not have any analytic records for the above patients showing that the sperm count was performed by repeating the count with another drop of the specimen. c. The laboratory's testing declaration form, signed by the laboratory Director on May 25, 2018, stated that the laboratory performs 450 semen analysis 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</p>

methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory procedure and patient testing records, lack of analytical test records, and interview with the laboratory manager and staff, the laboratory Director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: a. 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 policy and procedure, lack of approved written documentation, and interview with the laboratory manager, the laboratory Director failed to assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The findings include: a. The laboratory has a licensed CLS, few unlicensed personnel and a consultant who are involved in patient management and laboratory testing, however, the laboratory director had not assigned, in writing, to any person of their responsibilities and duties. b. On May 25, 2018 at 3: 15 pm laboratory manager and staff affirmed that the laboratory director did not assign duties/responsibilities, in writing, to personnel. c. The laboratory's testing declaration form, signed by the laboratory Director on May 25, 2018, stated that the laboratory performs 2750 tests annually.