

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0883366	(X3) Date Survey Completed 02/16/2022
Name of Provider or Supplier Fertility Center Of California	Street Address, City, State 6699 Alvarado Rd, Ste 2208, 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
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the California LFS (Laboratory Field Services) form 116, it was determined that the laboratory test personnel (LP) is using a TRL (training) license to perform high complexity testing (semen analysis). The laboratory inspection occurred on 2/16/22 between 9 a.m. and 11 a.m. Findings include: 1. The laboratory director is responsible for ensuring that prior to testing specimens, all personnel have the appropriate education and experience. 2. See Dtag 6170.</p>
D6170	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the California LFS (Laboratory Field Services) form 116, it was determined that the laboratory test personnel (LP) is using a TRL (training) license to perform high complexity testing (semen analysis). The laboratory inspection occurred on 2/16/22 between 9 a.m. and 11 a.m. Findings include: 1. Testing personnel performing high complexity testing in California are required to have a current license</p>

(CLS) issued by the California Laboratory Field Services Department. 2. The LP is currently performing semen analysis, which is a high complexity test. 3. The LP listed is not licensed for performing high complexity testing. 4. The LP has a training license, and is only permitted for training, not working, as a laboratory scientist. The training license permits training only in a LFS Department approved CLS training programs. 5. A review of the LFS personnel licensing section for the LP indicates the training license was initially applied for in 2013 and CLS training has not been completed.