

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2009927	(X3) Date Survey Completed 08/18/2021
Name of Provider or Supplier California Center For Reproductive	Street Address, City, State 477 El Camino Real, Ste C310, Encinitas, 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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 procedure documentation and an interview with the general supervisor (GS), it was determined that the laboratory director failed to ensure that the competency reports were completed for the testing personnel (TP). The laboratory inspection occurred on 8/18/21 between 3:00 and 4:00 p.m. Findings include: 1.The GS was asked to produce competency reports for the TP for 2019 and 2020. 2.The GS indicated on 8/18/21 at 3:45 p.m. that the competency reports for 2019 and 2020 were not available.</p>