

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0946046	<b>(X3) Date Survey Completed</b>  10/19/2018
<b>Name of Provider or Supplier</b>  Valley Center For Reproductive Health, Inc	<b>Street Address, City, State</b>  4835 Van Nuys Blvd, Ste 200 B, Sherman Oaks, 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>D2098</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the second quarter (Q2-2018) of the American Proficiency Institute (API) , CMS Casper Report 0096D proficiency testing records, and interview with the laboratory director, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Free Thyroxine, Human Gonadotrophin Hormone (HCG), and Thyroid Stimulating Hormone (TSH) analytes. The findings included: a. Q2-2018, API reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: HCG 0% Q2-2018 Free Ty 0% Q2-2018 TSH 0% Q2-2018 b. Based on the laboratory's annual testing declaration submitted for 2017 to 2018, the laboratory analyzed and reported, 105 Free Thyroxine, 487 HCG, and 250 TSH tests that cannot be assured due to the proficiency testing failures. c. The laboratory director confirmed (10/19/2018, 1500) that the laboratory received the above unsatisfactory proficiency testing scores.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 review of the first quarter (Q1-2018), second quarter (Q2-2018) of the American Proficiency Institute (API), proficiency testing records, random patient</p>

sampling test results for Estradiol, and interview with the laboratory director, it was determined that the laboratory failed to attain 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. Q1-2018, Q2-2018, API reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Estradiol 67% Q1-2018 Prolactin 67% Q1-2018 Free T3 0% Q2-2018 b. For eight (8) out of nine random patient sampling test results covering period from 1/16/2018 to 10/1/2018, eight (8) patients have been analyzed and reported for Estradiol which results cannot be assured. c. Based on the testing declaration submitted for 2017 to 2018, the laboratory analyzed and reported sixty eight (68) Prolactin, and 94 Free T3 patient test results that cannot be assured. d. The laboratory director confirmed (10/19/2018, 1500) that the laboratory received the above unsatisfactory proficiency testing scores.