

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0936846	<b>(X3) Date Survey Completed</b>  06/07/2022
<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>D2099</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Association of Bioanalysts (AAB) proficiency testing reports, review of five (5) randomly selected patient result records from 2/19 /2021 to 5/27/2022, and interview with the laboratory's technical supervisor (TS) and testing person (TP), the laboratory failed to attain a score of at least 80 percent for Endocrinology for Human Chorionic Gonadotropin (hCG) for the first event of 2022 (Q1-2022). The findings included: 1. AAB reported for Q1-2022 a score of 60% for the analyte hCG. 2. The TS and TP confirmed on June 7, 2022, at approximately 11: 45a.m. that the laboratory had failed to attain a proficiency score of at least 80 percent for the analyte hCG. 3. Based on the laboratory's annual test volume declaration signed by the laboratory director on 05/24/2022 the laboratory analyzed and reported approximately 2,500 Endocrinology tests which include hCG.</p>
<b>D6089</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's policy &amp; procedures and proficiency testing records, and interview with the laboratory technical supervisor on June 7, 2022; it was determined that the laboratory director, failed to ensure that PT samples</p>

for Endocrinology for the first event of 2022 were tested as required under subpart H. of this part. See D2099.