

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0936846	(X3) Date Survey Completed 11/23/2020
Name of Provider or Supplier Pacific Reproductive Center	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2098	<p>ENDOCRINOLOGY 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 Surveyor review of laboratory's policy & procedure, random patient, quality control (QC) and proficiency testing (PT) records for the years of 2019 and 2020, and interview with the laboratory testing person (TP) on November 23, 2020 at 12:05 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Human Chorionic Gonadotropin (hCG) at 1 testing event out of 4 events, reviewed. The findings include: 1. The laboratory participated in the AAB PT program for the years of 2019 and 2020. It received a score of 60% for the analyte hCG at the 1st event in 2019. 2. The laboratory TP on November 23, 2020 at 12:05 pm, affirmed that the laboratory did not receive at least 80% score for hCG at the 1st event in 2019. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/20/2020, stated that the laboratory performs 24,000 tests in endocrinology, annually.</p>
D2105	<p>ENDOCRINOLOGY CFR(s): 493.843(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, proficiency testing (PT) performance review and corrective actions records for the years of 2019 and 2020, and interview with the laboratory testing person (TP) on November 23, 2020 at 12:05 pm, the laboratory failed to undertake any remedial actions or training for unsatisfactory analyte performance for 1 events out of 4 events, reviewed. The findings include: 1. The laboratory participated in the AAB PT program for the years of 2019 and 2020, and obtained an unsatisfactory analyte performance for the analyte hCG. The laboratory received a score of 60% for the analyte hCG at the 1st event in 2019 which is an unsatisfactory analyte performance. However, it did not take any remedial actions or training for unsatisfactory analyte performance. 2. The laboratory TP on November 23, 2020 at 12:05 pm, affirmed that the laboratory did not take any remedial actions or training for the unsatisfactory analyte performances in 2019. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/20 /2020, stated that the laboratory performs 24,000 tests in endocrinology, annually.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, PT records for the years of 2019 and 2020, and interview with the laboratory TP on November 23, 2020 at 12:05 pm, the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for 1 PT event out of 4 events, reviewed. The findings include: The laboratory director or an appropriate staff did not review the received AAB PT reports on 1 occasion that required corrective actions. The laboratory received 60% score for the analyte hCG at the 1st event in 2019 which was an unsatisfactory analyte performance and required a corrective action. However, the laboratory director or an appropriate staff did not investigate or take any corrective actions for the failure.