

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2038078	(X3) Date Survey Completed 05/10/2021
Name of Provider or Supplier Pacific Reproductive Center	Street Address, City, State 381 Corporate Terrace, Corona, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CAP (College of American Pathologists) proficiency testing (PT) result reports, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to ensure and to verify the accuracy of any analyte, assigned a proficiency testing score/grade that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring/grading as specified in subpart I of this part 42 CFR part 493, or the laboratory receives a zero score for nonparticipation, or late return or results). The findings included: a. The laboratory performed Semen analysis (SA) and elected to participate CAP SPCD (Sperm Morphology & Motility Online) PT program to perform its evaluation of proficiency testing performance and to ensure accuracy, reliability and timely for SA testing. b. The SPCD PT program includes Sperm count, quant; Sperm motility WHO5 (%); Forward Progression WH (%); Non-Progressive WHO5 (%); and Percent of normal sperm (%) Norm. c. The laboratory affirmed (5/10/21 @ 10:55 am) that the laboratory obtained "Exceptional Reason Code" [26] which indicated the grading is for "Educational". The CAP PT program did not obtain the agreement required for grading for Sperm motility WHO5; Forward Progression WH; and Non-Progressive WHO5 in the SPCD-A 2020 PT event. d. The laboratory failed to take actions to evaluate, ensure and verify the accuracy of the testing result reports. e. The laboratory performed in approximately 33 patient samples monthly.</p>

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) result reports by AAB (American Association of Bioanalysts) and CAP (College of American Pathologist), and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to ensure, and to verify, at least twice annually, the accuracy of any test or procedure it performed that is not included in subpart I of this part, 42 CFR part 493. The findings included: a. The laboratory performed serum Progesterone and Semen Analyses (SA) onsite, which are not included in subpart I of 42 CFR part 493. b. The laboratory elected to perform the evaluation of proficiency testing performance for serum Progesterone with AAB, and for SA with CAP SPCD PT programs to ensure, at least twice annually, the accuracy, reliability, and timeliness of the testing procedures. c. The laboratory attained a score of 0 % for serum Progesterone in the Q3 2019 AAB Fertility-Endocrinology PT event, which was unsatisfactory performance. d. The laboratory obtained a grade of "unacceptable", one out of two challenges (i.e., 50%) for "Percent of normal sperm" in the SPCD--A 2020 CAP PT event, which was unsatisfactory performance. e. The TP affirmed (5/10/2021 @ 11:55 am) that the laboratory attained a score of 0 % in Q3 2019 AAB Fertility-Endocrinology PT event, which was unsatisfactory performance. f. The TP affirmed (5/10/2021 @ 11:55 am) that the laboratory attained a grade of unacceptable for Percent of normal sperm in SPCD-A 2020 CAP PT event, which was unsatisfactory performance. g. The laboratory performed serum Progesterone and SA in approximately 25 and 33 patient samples per month, respectively.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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, accurately, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing result reports by AAB (American Association of Bioanalysts) and CAP (College of American Pathologist), and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure and to verify that the proficiency testing samples were tested as required by the evaluation of proficiency testing performance. The findings included: a. The laboratory director failed to be responsible for the technical operations and failed to ensure the laboratory performed the PT as required. b. The laboratory performed serum Progesterone and Semen Analyses (SA) onsite, which are not included in subpart I of 42 CFR part 493. c. The laboratory failed to attain

acceptable scores and/or grades in its AAB and CAP PT challenges and failed to take actions for the failures in quality in the years of 2019 and 2020 PT challenges, see D-5215, and D-5217.