

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1082600	(X3) Date Survey Completed 05/18/2021
Name of Provider or Supplier Pacific Reproductive Center	Street Address, City, State 10 Post Ste 100, Irvine, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 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 Semen Analyses testing procedure the laboratory performed twice annually. The findings included: a. The laboratory performed Semen analysis (SA), which is not list in the subpart of I in 42 CFR part 493. b. The laboratory elected to participate CAP Sperm Morphology & Motility Online (SPCD) PT program for the evaluation of proficiency testing performance, and to ensure the accuracy of its SA testing procedures. c. The CAP SPCD PT program provides two samples each challenges in 2019 and 2020 for the testing including, Sperm count, quant, Sperm motility WHO5, Forward Progression WH, Non Progression WHO5, Percent of normal s Strict (Kruger), Percent of normal sperm Strict (Kruger) with grading of "Acceptable" or "Unacceptable" for the test results. d. The laboratory failed to participate in the 2019 SCPD-A PT challenge and received an "Exception Reason Code" [40] which indicated "Results for this kit were not received." which was unsatisfactory performance for the SPCD-A 2019 PT event. e. The laboratory attained one unacceptable Sperm count, quant, for SCPD-06, in the SPCD-B 2019 PT, which was unsatisfactory performance for that event. f. The laboratory attained unacceptable for both of two samples, SCPD-03D and -04D, in the SPCD-A 2020 PT for Percent of normal sperm, which was unsatisfactory performance for that event. g. The laboratory TP affirmed (5/18/21 @ 11:5 am) that the laboratory attained [40] for the SPCD-A 2019 PT test result report. h. The laboratory testing personnel affirmed (5/18/21 @ 11: 15 am) that the laboratory attained one unacceptable Sperm count, count for the</p>

SPCD-A 2019 PT event. i. The laboratory TP affirmed (5/18/21 @ 11:20 am) that the laboratory attained "unacceptable" grades for Percent of normal sperm for both of two samples, SCPD-03D and -04D, in the SPCD-A 2020 PT for Sperm count, quant which was unsatisfactory performance for that event. j. The laboratory performed SA in approximately 33 patient samples monthly.

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, accurate, 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 CAP (College of American Pathologists) proficiency testing (PT) result reports, 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 and reported as instructed. The findings included: a. The laboratory director failed to be responsible for the laboratory technical operation and failed to ensure and to verify that the proficiency testing samples were tested and reported as instructed. b. The laboratory performed Semen analysis (SA), which is not list in the subpart of I in 42 CFR part 493. c. The laboratory elected to participate CAP Sperm Morphology & Motility Online (SPCD) PT program for the evaluation of proficiency testing performance, and to ensure the accuracy of its SA testing procedures. d. The laboratory attained an "Exception Reason Code" [40] which indicated "Results for this kit were not received." which was unsatisfactory performance for SPCD-A 2019 PT event, see D 5217. e. The laboratory attained unacceptable grade for SPCD-B 2019 and SPCD-A 2020 PT challenges see. D-5217.