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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D2060022 | (X3) Date Survey Completed 07/29/2025 |
| Name of Provider or Supplier Pacific Reproductive Center | Street Address, City, State 116 E Broadway Blvd Ste 300, Glendale, 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 |
|---------------------------|---|
| D2014 | <p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on review of 2023 - 2025 CAP (College of American Pathologists) proficiency testing reports, the lack of laboratory proficiency testing records, the lack of Attestation statements signed by the Laboratory Director and the Testing Person, and interview with the Testing Person, it was determined that the laboratory failed to document each step in the testing and reporting of proficiency testing samples for Semen Analysis, including the laboratory Worksheet for recording data and calculations, and the CAP form for reporting proficiency testing results. Findings included: 1. The laboratory chose to participate in CAP's proficiency testing program titled "SPCD, Sperm Morphology & Motility Online". 2. CAP proficiency testing Evaluation reports documented the laboratory reported results for Event B of 2023, Event B of 2024, and Event A of 2025. 3. For 3 out of 3 Events, the laboratory failed to have all proficiency testing records, as follows: a. CAP instructions for viewing the test samples online. b. Laboratory worksheets for recording data, such as Sperm Counts in duplicate, and calculations, such as % Motility. c. CAP form for recording and reporting test results. d. Confirmation that proficiency test results reported online successfully, with date reported. e. CAP Attestation forms signed by the Laboratory Director and the Testing Person documenting that proficiency testing samples were tested in the same manner as patients specimens by personnel routinely doing the</p> |

testing. 4. The reliability and quality of results reported to CAP in 2023, 2024, and 2025 could not be assured without all laboratory proficiency testing records for reference. .

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 CAP proficiency testing reports, the lack of laboratory records, and interviews with the Testing Person and CAP, it was determined that the laboratory failed to verify the accuracy of it's Semen Analysis at least twice annually in 2023 and 2024. Findings included: 1. The laboratory chose to participate in CAP's proficiency testing program titled "SPCD - Sperm Morphology & Motility Online" as the means to fulfill the requirement to verify the accuracy of it's Semen Analysis at least twice annually. 2. There were no CAP Evaluation reports documenting the laboratory reported proficiency testing results for Sperm Count, quantitative and qualitative, Motility, and Morphology for Event A of 2023 and Event A of 2024. 3. The Testing Person affirmed (7/29/25 at 2:30 PM) the aforementioned lack of proficiency testing records, stating no CAP samples were received. 4. CAP's Technical Support affirmed (by phone 800-323-4040 on 8/04/25 at 10:07 AM) the laboratory didn't participate in Events A of 2023 and 2024. 5. The laboratory failed to have laboratory records documenting an alternate method of verifying the accuracy of it's Semen Analysis in 2023 and 2024; and thus, failed to verify the accuracy of test results at least twice each year. 6. The reliability and quality of results reported during 2023 - 2024 for Semen Analysis: Sperm Count, Motility, and Morphology could not be assured. The laboratory reported 250 Semen Analyses annually (CMS116 CLIA Application, 7/14 /25). Eight laboratory records randomly selected for review are, as follows: Date Accession number ----- 3/02/23 030223- 2 4/27/23 042723- 2 5/11/23 051123- 5 6/08/23 060823- 1 3/14/24 031424- 3 3/28/24 032824- 2 3/28/24 032824- 8 7/17/24 071724- 412 .

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on the findings and deficiencies cited for failing to retain all CAP and laboratory proficiency testing records and the failure to at least twice annually verify the accuracy of it's Semen Analysis, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory and establishing regular self audits to assess the quality of laboratory processes and identify failures as they occur. Findings included: 1. For the duration of two years in 2023 - 2024, the laboratory failed to retain all CAP and laboratory proficiency testing records. See D2014. 2. For the duration of two years in 2023 - 2024, the laboratory failed to at twice annually verify the accuracy of it's Semen Analysis. See D5217.