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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0937925 | (X3) Date Survey Completed 05/10/2018 |
| Name of Provider or Supplier Reproductive Science Center Of The Bay Area | Street Address, City, State 100 Park Pl, Ste 200, San Ramon, 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 first quarter (Q1-2016) Sperm Viability, first quarter (Q1-2017) Sperm Count, Traditional, of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results , and interview with the technical supervisor, it was determined that the laboratory failed to verify the accuracy of the above analytes with an artificial scores of 100%. The findings included: Q1-2016 a. AAB reported the following artificial score of 100% proficiency testing score. Analyte: Value Acceptable Sperm Reported: Range: Viability Spec#1? 2 20-40 Spec#2? 6 18-39 Note: True score should have been 0% Q1-2017 Analyte: Value Acceptable Sperm Reported: Range: Count Spec#1? 8 9-23 Note: True score should have been 50% b. For four (4) out of four (4) random patient sampling test results reviewed covering period from 2/4/2016 to 4/16/2018, the laboratory analyzed and reported semen analysis consisting Sperm Count and Sperm Viability that could have been affected by the artificial scoring of 100%. c. The technical supervisor affirmed (5/10/2018, 1300), that the laboratory received the above artificial 100% scores for the above analytes without any corrective actions taken by the laboratory.</p> |
| 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</p> |

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 second quarter (Q2-2016) Sperm Viability of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to 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. The findings included: a. Q2-2016, AAB reported an unsatisfactory score of 0% for the Sperm Viability. b. For four (4) out of four (4) random patient sampling test results reviewed covering period from 2/4/2016 to 4/16/2018, the laboratory analyzed and reported semen analysis consisting of Sperm Viability even though the laboratory received an unsatisfactory proficiency testing score. c. The technical supervisor affirmed (5/10/2018, 1300), that the laboratory received the above unsatisfactory proficiency testing score.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review and the lack of documentation of a corrective action when the laboratory receives an artificial 100% scores for proficiency testing results and interview with the technical supervisor, it was determined that the laboratory has not established and document corrective action for an artificial 100% proficiency testing scores. See D 5215.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review and the lack of documentation of a corrective action when the laboratory receives an artificial 100% scores for proficiency testing results and interview with the technical supervisor, it was determined that the laboratory director

failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5215, D 5781.