

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2021812	(X3) Date Survey Completed 03/03/2022
Name of Provider or Supplier American Reproductive Centers - Ps	Street Address, City, State 1180 N Palm Canyon Dr, Palm Springs, 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 laboratory's proficiency testing (PT) result reports, and interview with the testing personnel, it was determined that the laboratory failed to verify the accuracy of semen analysis testing which is not included in subpart 42 CFR part 493, at least twice annually. The findings included: a. The laboratory performed semen analysis which is not included in subpart I of 42 CFR part 493. b. To perform "Evaluation of Proficiency Testing Performance" at least twice annual to verify the accuracy of its semen analysis testing which reports including but not limited to Sperm Motility, Sperm Morphology. c. The laboratory elected to enroll "Embryology, Andrology & Fetal offered by American Association of Bioanalysts (AAB) PT program. d. The laboratory attained a score of 50 % of Sperm Motility test in S1 2021 PT event which was unsatisfactory performance. e. The laboratory performed Sperm Motility in approximately 30 patient samples monthly.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and</p>

precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory patient test result reports, the semen analysis sperm count quality control (QC) records, and interview with the testing personnel (TP), it was determined that the laboratory failed to perform and document QC to detect immediate errors that occur due to adverse environmental conditions, and operator performance, and failed to monitor over time the accuracy and precision of test performance that may be influenced by changes in environmental conditions, and variance in operator performance, and failed to document all control procedures performed. The findings included: a. The laboratory performed semen analysis and reported the test results including but not limited to the following: Sperm Count, Sperm Morphology, Sperm Motility. b. Randomly sampled and reviewed 6 patient's semen analyses reports identified as follows: Date of service ID 1. 5/17/2021 S21 - 135 2. 5/26/2021 S21 - 150 3. 5/27/2021 S21 - 153 4. 2/24/2022 S22 - 36 5. 2/24/2022 S22 - 48 6. 2/28/2022 S22 - 57 c. Review "Accu-Beads for Manual Sperm Counting" records of May 2021 and February 2022. d. Noted that the laboratory had patient semen analyses result reported on 5/26/2021 S21-150 (#2 item b), no QC results documented on the May 2021 QC records. e. Noted that the laboratory had patient semen analyses result reported on 2/28/2022 S22 -57 (#6 item b), no QC results documented on the February 2022 QC records. f. The TP affirmed (3/3/2022 @11:15 AM) that no Accu-Beads QC count recorded for both days of 5/17/2022 and 2/28/2022.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assurance (QA) form, titled as "Quality Control Form for Andrology" records, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems. The findings included: a. The laboratory failed to perform Accu-Bead QC for sperm count, see D-5441. b. The laboratory established a quality assurance (QA) form titled as "Quality Control Form for Andrology" which consists of 10 questions to verify and assure the consistency and accuracy of the patient final test result reports. c. The laboratory established the questions, including but not limited to the following to assure and to verify the consistency and accuracy of the patient test result reports: Is requisition form signed by the physician attached? Are all calculations correct in the related section? Is the comparison made between the work sheet and data generated on computer? d. The laboratory failed to follow its QA for "Quality Control Form for Andrology", see D-5893 e. The laboratory failed to ensure the accuracy and consistency of the testing result data records between the worksheet and the final patient result reports. f.

Randomly sampled and reviewed 6 patient's semen analyses reports identified as follows: Date of service ID 1. 5/17/2021 S21 - 135 2. 5/26/2021 S21 - 150 3. 5/27/2021 S21 - 153 4. 2/24/2022 S22 - 36 5. 2/24/2022 S22 - 48 6. 2/28/2022 S22 - 57 g. Review of 5/17/2021 S21 - 135, the laboratory failed to assure the consistency of its calculation for sperm morphology expressed in % for Read 1 and Read 2. "Morphology" in the worksheet as follows: Expressed in % for: Norm = Normal forms; AbnH = Abnormal Head; AbnM = abnormal Mid Piece; AbnT = Abnormal Tail; R = Read, Ave = Average; FTR = Final Test Report % R1 R2 Ave Norm 5 7 6 AbnH 26 58 57 AbnM 12 16 13 AbnT 25 23 24 _____ 98% 104% 100% h. Review of 5/26/2021 S21 - 150, the laboratory failed to assure the consistency of its calculation for sperm morphology expressed in % for Read 1 and Read 2. "Morphology" in the worksheet as follows: % R1 R2 Ave FTR Norm 4 6 5 5 AbnH 62 64 63 63 AbnM 7 9 8 7 AbnT 26 24 25 25 _____ 99% 103% 101% 100%

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory patients' semen analysis final test result reports, and interview with the testing personnel (TP), it was determined that the laboratory failed to perform the postanalytical systems quality assessment effectively to assure consistency and the accuracy of the patient test result reports. The findings included:
a. The laboratory performed semen analysis and report the test results including but not limited to the following: Sperm Count, Sperm Morphology, Sperm Motility. b. The laboratory performed quality assurance (QA) but failed to ensure the accuracy and consistency of the testing result data records between the worksheet and the final patient result reports. c. Randomly sampled and reviewed 6 semen analyses reports identified as follows: Date of eservice ID 1. 5/17/2021 S21 - 135 2. 5/26/2021 S21 - 150 3. 5/27/2021 S21 - 153 4. 2/24/2022 S22 - 36 5. 2/24/2022 S22 - 48 6. 2/28/2022 S22 - 57 d. Review of 5/17/2021 S21 - 135, the laboratory failed to assure the consistency and accuracy of its calculation for sperm morphology expressed in % for Read 1 and Read 2. "Morphology" in the worksheet as follows: Expressed in % for: Norm = Normal forms; AbnH = Abnormal Head; AbnM = abnormal Mid Piece; AbnT = Abnormal Tail R = Read, Ave = Average; FTR = Final Test Report % R1 R2 Ave Norm 5 7 6 AbnH 26 58 57 AbnM 12 16 13 AbnT 25 23 24 _____ 98% 104% 100% e. Review of 5/26/2021 S21 - 150, the laboratory failed to assure the consistency and accuracy of its calculation for sperm morphology expressed in % for Read 1 and Read 2. "Morphology" in the worksheet as follows: % R1 R2 Ave FTR Norm 4 6 5 5 AbnH 62 64 63 63 AbnM 7 9 8 7 AbnT 26 24 25 25 _____ 99% 103% 101% 100%

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure 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 (PT) result reports and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure the proficiency testing samples were tested as required to ensure the accuracy, reliability, timely of the patient testing result reports. The findings included: a. The laboratory performed semen analysis which is not included in subpart I of 42 CFR part 493. b. The laboratory director failed to ensure the laboratory performed "Evaluation of Proficiency Testing Performance" at least twice annually to verify the accuracy of its semen analysis testing which reports including but not limited to Sperm Motility, Sperm Morphology. c. The laboratory elected to enroll "Embryology, Andrology & Fetal offered by American Association of Bioanalysts (AAB) PT program for semen analysis testing system and to ensure the accuracy, reliability of the patient testing result reports, see D-5217.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 review of the patient semen analyses records, the laboratory's proficiency testing (PT) result reports, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory performed semen analysis which is not included in subpart I of 42 CFR part 493. b. The laboratory director failed to ensure that the laboratory performed "Evaluation of Proficiency Testing Performance" at least twice annual to verify the accuracy of its semen analysis testing which reports including but not limited to Sperm Motility, Sperm Morphology, See D-5217. c. b. The laboratory director failed to ensure the consistency and accuracy of the testing result data records between the worksheet and the final patient result reports, see D-5441 d. The laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur, see D-5791

D6095

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on review of the patient semen analyses records, and interview with the testing personnel (TP), it was determined that the laboratory director failed to ensure the

establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory performed semen analysis which is not included in subpart I of 42 CFR part 493. b. The laboratory director failed to ensure the consistency and accuracy of the testing result data records between the worksheet and the final patient result reports, see D-5441 c. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system, see D-5791.