Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2022054	(X3) Date Survey Completed 07/05/2018
Name of Provider or Supplier American Reproductive Centers Inc	**Street Address, City, State** 1640 Newport Blvd Ste 150, Costa Mesa, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to monitor and document the temperature conditions. The findings included: a. The laboratory established an acceptable room temperature range between 21 to 28 centigrade (oC). b. Reviewed the laboratory temperature records, there were 9 out of a total of 22 temperature recorded in April 2018 at 20 oC which was out of the acceptable range. c. Reviewed the laboratory temperature records, there were 5 out of a total of 19 temperature recorded in May 2018 at 20 oC which was out of the acceptable range. d. The laboratory performed complete semen analysis, the temperature monitoring is essential for proper storage of the specimen, and to ensure accurate and reliable test system operation, and test results reporting. e. The laboratory staff affirmed (7/5/18 @ 11:05 AM) that no remedial actions were taken to correct the temperatures out side the acceptable room temperature. f. The laboratory performed complete semen analyses in approximately 30 patient specimens monthly
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 of the temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when any of the following occur when the test systems did not meet the laboratory's verified or established performance specifications, which include but are not limited to temperature. The findings included: See D-5413
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 laboratory temperature records, and interview with the laboratory staff, 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: See D-5781