Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1080607	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Red Rock Fertility Center	9120 W Russell Rd Ste 200, Las Vegas, NV	

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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA validation survey conducted at your facility on April 13, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory records for the 2022 American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, a review of the director approved proficiency testing policy and procedure, and an interview with the laboratory manager, the laboratory failed to retain the testing records for the 2022 test events S-1-Andrology, and S-2-Andrology for a minimum of two years. Findings include: 1. There were no records, including the signed attestation, the result reporting form, and the evaluation of the results from the PT agency, for the 2022 AAB Proficiency test events for S-1-Andrology and S-2-Andrology for the sperm count,

	sperm motility and sperm morphology tests. 2. The director approved proficiency testing policy stated in section V. Record File, "The laboratory's proficiency testing record file should contain the report form copy, procedural documentation, evaluation report, and summary report for each mailing for a period of at least two years." 3. The laboratory manager confirmed the findings during an interview conducted on April 13, 2023 at approximately 11:15 AM. The laboratory performs approximately 240 hematology tests annually.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: General Laboratory Systems was not met. The laboratory failed to evaluate proficiency testing performance (Refer to D5215), the laboratory failed to at least twice annually verify the accuracy of tests or procedures it performs that are not included in subpart I (Refer to D5217), and the laboratory failed to document review of and corrective action taken for all unsatisfactory proficiency testing scores (Refer to D5221).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on a review of the 2021 American Association of Bioanalysts (AAB) Proficiency Testing (PT) and 2022 College of American Pathologists (CAP) Proficiency Testing (PT) laboratory records, a review of the director approved proficiency testing policy and procedure, and an interview with the laboratory manager, the laboratory failed to ensure ungraded results were reviewed against the participant or data summary for acceptability. Findings include: 1. There was no documentation of a review of the AAB data summary for the 2021 AAB Andrology test event S-2 for the lack of consensus determination for the sperm motility for specimen number 6. 2. There was no documentation of a review of the CAP participant summary for the specimen K-04 quantitative serum hCG result that was reported on the the 2022 CAP Ligand-General test event K-A. A review of the test event records revealed that the serum quantitative hCG result for specimen K-04 was not graded due to insufficient peer group data. According to the record, nine laboratories using the Roche Cobas e411/Elecsys reported results for specimen

	number K-04. 3. There was no documentation of a review of the CAP participant summary for specimens Y-02 and Y-03 estradiol results that were reported on the 2022 CAP Sex Hormones Y-A test event. A review of the test event records revealed that the estradiol results reported for each specimen were greater than the reportable range of 3000 pg/mL on the Roche Cobas e411/Elecsys. The laboratory manager stated that the laboratory reports >3000 pg/mL on patient results greater than the reportable range during an interview on April 13, 2023 at approximately 10:30 AM. 4. A review of the director approved policy and procedure for proficiency testing stated in section IV. Unacceptable Proficiency Testing Result Form, "Results not graded because of lack of consensus, or because the laboratory submitted its results after the cut-off date for receipt, did not submit results or made an error in completing the result form should also be documented and corrected." 5. The laboratory manager confirmed the findings during an interview conducted on April 13, 2023 at approximately 11:30 AM. The laboratory performs approximately 850 endocrinology tests and 250 hematology tests annually.
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 a review of the 2021 American Association of Bioanalysts (AAB) Proficiency Testing (PT) laboratory records, a review of the 2021 and 2022 College of American Pathologists (CAP) Proficiency Testing (PT) laboratory records, and an interview with the laboratory manager, the laboratory failed to ensure that the accuracy of all tests performed that are not included in subpart I were verified at least twice annually. Findings include: 1. A review of the 2021 AAB PT Andrology event S-1 and S-2 revealed that the laboratory obtained a score of 100% for the sperm count on test event S-1 and a score of 50% for the sperm count on test event S-2. There was no documentation of an alternative proficiency test or twice per year verification of accuracy for the sperm count in 2021. 2. A review of the 2021 CAP PT Ligand-Special test events A and B revealed that the laboratory obtained a score of 66% for the testosterone test on event Y-A, and a score of 100% on event Y-B. There was no documentation of an alternative proficiency test or twice per year verification of accuracy for the testosterone in 2021. 3. A review of the 2021 CAP PT Ligand-Special test events A and B revealed that the laboratory obtained a score of 100% for the progesterone test on event Y-A, and a score of 66% on event Y-B. There was no documentation of an alternative proficiency test or twice per year verification of accuracy for the progesterone in 2021. 4. A review of the 2022 CAP PT Sex Hormones test events A and B revealed that the laboratory obtained a score of 100% for the estradiol, lutenizing hormone (LH), Prolactin, and testosterone tests on event Y-A, and a score of 66% for each of the tests on event Y-B. There was no documentation of an alternative proficiency test or twice per year verification of accuracy for the estradiol, lutenizing hormone (LH), Prolactin, and testosterone in 2022. 5. The laboratory manager confirmed the findings during an interview conducted on April 13, 2023 at approximately 11:45 AM. The laboratory performs approximately 850 endocrinology tests and 250 hematology tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2021 and 2022 College of American Pathologists (CAP) Proficiency Testing (PT), a review of the director approved proficiency testing policy and procedure, and an interview with the laboratory manager, the laboratory failed to ensure that corrective action was documented for all PT results that were unacceptable. Findings include: 1. There was no documentation of corrective action for unacceptable proficiency testing results for the following test events and analytes: Year Test Analyte Specimen Score Event 2022 Sex Testosterone Y-02 33% Hormone Y-A 2022 Sex Testosterone Y-03 33% Hormone Y-A 2021 Ligand- Testosterone Y-03 66% Special Y-A 2021 Ligand- Progesterone Y-06 66% Special Y-B 2. The director approved proficiency testing policy and procedure stated in section IV. Unacceptable Proficiency Testing Result Form, "The unacceptable proficiency testing result form is necessary so the laboratory can document its evaluation of unacceptable proficiency testing results and any corrective actions taken." 3. The laboratory manager confirmed the findings during an interview conducted on April 13, 2023 at approximately 11:30 AM. The laboratory performs approximately 850 endocrinology tests annually.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of the 2021 and 2022 College of American Pathologists (CAP) Proficiency Testing (PT) records, a review of the 2021 American Association of Bioanalysts (AAB) PT records, a review of the director approved Proficiency Testing policy and procedure, and an interview with the laboratory manager, the director failed to ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify problems that require corrective action. Findings include: 1. There was no documentation of a review of the AAB data summary for the 2021 AAB Andrology test event S-2 for the lack of consensus determination for the sperm motility for specimen number 6. 2. There was no documentation of a review of the CAP participant summary for the specimen K-04 quantitative serum hCG result that was reported on the the 2022 CAP Ligand-General test event K-A. A review of the test event records revealed that the serum quantitative hCG result for specimen K-04 was not graded due to insufficient peer group data. According to the record, nine laboratories using the Roche Cobas e411/Elecsys reported results for specimen number K-04. 3. There was no documentation of a review of the CAP participant summary for specimens Y-02 and Y-03 estradiol results that were reported on the 2022 CAP Sex Hormones Y-A test event. A review of the test event records revealed that the estradiol results reported for each specimen were greater than the reportable range of 3000 pg/mL on the Roche Cobas e411/Elecsys. The laboratory manager stated that the laboratory reports >3000 pg/mL on patient results greater than the reportable range during an interview on April 13, 2023 at approximately 10:30 AM. 4. A review of the director approved policy and procedure for proficiency testing stated

	in section IV. Unacceptable Proficiency Testing Result Form, "Results not graded because of lack of consensus, or because the laboratory submitted its results after the cut-off date for receipt, did not submit results or made an error in completing the result form should also be documented and corrected." 5. The findings were confirmed during an interview with the laboratory manager on April 13, 2023 at approximately 11:00 AM. The laboratory performs approximately 850 endocrinology tests and 250 hematology tests annually.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the 2021 and 2022 College of American Pathologists (CAP) Proficiency Testing records, a review of the director approved policy and procedure for Proficiency Testing, and an interview with the laboratory manager, the director failed to ensure that an approved corrective action plan was followed when any proficiency testing results were found to be unacceptable or unsatisfactory. Findings include: 1. There was no documentation of corrective action for unacceptable proficiency testing results for the testosterone specimens Y-02 and Y-03 on the 2022 Sex Hormones test event A, no documentation of corrective action for the unacceptable result for testosterone specimen Y-03 on the the 2021 Ligand-Special test event A, and no documentation of the unacceptable progesterone result reported for specimen Y-06 on the the 2021 Ligand-Special test event B. 2. The director approved proficiency testing policy and procedure stated in section IV. Unacceptable Proficiency Testing Result Form, "The unacceptable proficiency testing result form is necessary so the laboratory can document its evaluation of unacceptable proficiency testing results and any corrective actions taken." 3. The laboratory manager confirmed the findings during an interview conducted on April 13, 2023 at approximately 11:30 AM. The laboratory performs approximately 850 endocrinology tests annually.