Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2012262	12/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ou Medicine, Inc Reproductive Health	840 Research Parkway, Suite 200, Oklahoma City, OK	

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	The recertification survey was performed on 12/09/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and technical supervisor#2/technical consultant #2 at the conclusion of the survey.
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 records and interview with the laboratory direcor and technical supervisor#2/technical consultant #2, the laboratory director (or designee) and/or testing person(s) failed to sign proficiency testing attestation statements. Findings include: (1) During the survey, surveyor #1 reviewed 2018 and 2019 proficiency testing records and identified the following for 8 of 13 events: (a) First 2018 Embryology/Andrology Event (S1) - The attestation statement had not been signed by the laboratory director or designee; (b) First 2018 Ligand General Event (K-A) - The attestation statement had not been signed by the laboratory director or designee and the testing person(s); (c) Second 2018 Embryology/Andrology Event (S2) - The

	attestation statement had not been signed by the laboratory director or designee and the testing person(s); (d) Second 2018 Ligand Special (Y-B) - The attestation statement had not been signed by the laboratory director or designee and the testing person(s); (e) Third 2018 Ligand General Event (K-C) - The attestation statement had not been signed by the laboratory director or designee and the testing person(s); (f) First 2019 Embryology/Andrology Event (S1) - The attestation statement had not been signed by the laboratory director or designee and the testing person(s); (g) Second 2019 Embryology/Andrology Event (S2) - The attestation statement had not been signed by the laboratory director or designee and the testing person(s); (h) Second 2019 Ligand Special (Y-B) - The attestation statement had not been signed by the laboratory director or designee and the testing person(s). (2) Surveyor #1 reviewed the findings with the laboratory director and technical supervisor#2/technical consultant #2. Both stated the attestation statements had not been signed as indicated above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to have a written competency policy for the clinical consultant, technical consultant, technical supervisor, and general supervisor based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, surveyor #1 reviewed personnel records for competency assessments performed during 2018 and to date in 2019. There was no evidence competencies had been performed for the clinical consultant, technical consultant #2, technical supervisor #2, and general supervisor, based on their job responsibilities; (2) Surveyor #1 asked the laboratory director if a written policy to evaluate the positions based on job responsibilities was available and if competencies had been performed during the review period. The laboratory director stated a policy to evaluate the clinical consultant, technical consultant #2, technical supervisor #2, and general supervisor, based on job responsibilities had not been written; and competencies had not been performed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the laboratory director and technical supervisor #2/technical consultant #2 the laboratory failed to follow written procedures for complete semen analysis testing in the laboratory. Findings include: (1) At the beginning of the survey, the laboratory

	director stated that the laboratory performed a complete semen analysis. (2) Later during the survey, the surveyors reviewed the procedure titled, "Protocol # 1.1 Complete Semen Analysis" which stated: (a) Insure that the specimen is evaluated within 90 minutes of collection, with a goal of 60 minutes". (2) Surveyor #2 reviewed patient records from 10/01/19 through 12/02/19 and identified 109 of 184 patients did not meet the laboratory's goal of 60 minutes and 72 of 184 patients did not meet the allowable time limit of 90 minutes.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, policies and procedures and interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for obtaining a second sperm count reading. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyors that the laboratory used the Leja slides to perform a sperm count reading. (2) Later during the survey, surveyor #2 reviewed the manufacturer's instructions for obtaining a sperm count reading which stated: (a) "Count at least six different fields and 800-1000 cells for accuracy"; (b) "Repeat the process on a different chamber loaded with the same sample to get a second reading". (3) Surveyor #2 reviewed the written policies and procedures. The procedure titled, "Protocol #1.1 - Complete Semen Analysis" did not include instructions for obtaining a second sperm count reading as stated in the manufacturer's instructions for the Leja slides; (4) Surveyor #2 then reviewed records and identified a patient semen analysis performed on 11/01/19. The records did not include documentation that a second sperm count reading had been performed; (5) Surveyor #2 reviewed the records with the laboratory director and technical supervisor #2/technical consultant #2 who stated a second sperm count reading was not routinely performed.
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 a review of records, manufacturer's storage instructions, observation of the laboratory freezer and interview with the laboratory director and technical supervisor #2/technical consultant #2, the laboratory failed to ensure materials were being stored as required. Findings include: SANYO ULTRA LOW FREEZER (1) At the beginning

of the survey, the surveyors observed the contents of the Sanyo Ultra Low freezer in the laboratory. The following were examples of materials being stored in the freezer, along with the manufacturer's storage requirements: (a) 3 boxes of BioRad Liquichek Immunoassay Plus Control materials (Level 1 lot #40991, Level 2 lot# 40992, Level 3 lot#40993); the storage requirement was -70 to -20 degrees Centigrade (C). (2) The surveyors asked the laboratory director and technical supervisor #2/technical consultant #2 to explain what the materials were used for. The laboratory director and technical supervisor #2/technical consultant #2 stated the following: (a) The BioRad Liquichek Immunoassay Plus Control materials were used to perform quality control for endocrinology testing performed on the Immulite 1000 analyzer. (3) The surveyors then reviewed temperature records for 10 months (January 2019 through October 2019). It was identified that documented temperatures were colder than -70 degrees C (the coldest temperature allowed for the materials) for 10 of 10 months reviewed as follows: (a) January 2019 - 31 of 31 temperatures were documented as -80 degrees C or colder; (b) February 2019 - 28 of 28 temperatures were documented as -79 degrees C or colder; (c) March 2019 - 31 of 31 temperatures were documented as -78 degrees C or colder; (d) April 2019 - 30 of 30 temperatures were documented as -79 degrees C or colder; (e) May 2019 - 31 of 31 temperatures were documented as -80 degrees C or colder; (f) June 2019 - 30 of 30 temperatures were documented as -79 degrees C or colder; (g) July 2019 - 31 of 31 temperatures were documented as -80 degrees C or colder; (h) August 2019 - 31 of 31 temperatures were documented as -80 degrees C or colder; (i) September 2019 - 30 of 30 temperatures were documented as -79 degrees C or colder; (j) October 2019 - 31 of 31 temperatures were documented as -79 degrees C or colder; (4) The surveyors reviewed the records with the laboratory director and technical supervisor #2/technical consultant #2 who stated the materials had not been stored according to manufacturer's instruction. ENDOCRINOLOGY FRIGIDAIRE FREEZER (1) At the beginning of the survey, the surveyors observed the contents of the Endocrinology Frididaire freezer in the laboratory. The following were examples of materials being stored in the freezer, along with the manufacturer's storage requirements: (a) 3 boxes (9 bottles) of BioRad Liquichek Immunoassay Plus Control materials (Level 1 lot #40991, Level 2 lot# 40992, Level 3 lot#40993); the storage requirement was -70 to -20 degrees Centigrade (C); (b) 1 box of Siemens Immulite Systems Follicle-Stimulating Hormone Calibration Verification materials (lot# 0105); the storage requirement was -20 degrees C and colder; (c) 1 box of Siemens Immulite Systems Luteinzing Hormone Calibration Verification materials (lot# 0103); the storage requirement was -20 degrees C and colder; (d) 1 box of Siemens Immulite Systems Thyroid Stimulating Hormone Calibration Verification materials (lot# 0107); the storage requirement was -20 degrees C and colder; (2) The surveyors asked the laboratory director and technical technical supervisor #2/technical consultant #2 to explain what the materials were used for. The laboratory director and technical supervisor #2/technical consultant #2 stated the following: (a) The BioRad Liquichek Immunoassay Plus Control materials were used to perform quality control for endocrinology testing performed on the Immulite 1000 analyzer; (b) The Siemens Immulite Systems Follicle-Stimulating Hormone Calibration Verification materials were used to perform calibration; (c) The Siemens Immulite Systems Luteinzing Hormone Calibration Verification materials were used to perform calibration; (d) The Siemens Immulite Systems Thyroid Stimulating Hormone Calibration Verification were used to perform calibration. (3) The surveyors then reviewed temperature records for 10 months (January 2019 through October 2019). It was identified that documented temperatures were warmer than -20 degrees C (the warmest temperature allowed for the materials) for 10 of 10 months reviewed as follows: (a) January 2019 - 6 of 31 temperatures were documented as -19 degrees C (Days 7,9,12,15,23,25); (b) February 2019 - 6 of 28 temperatures were documented as -19 degrees C (Days

	3,5,7,11,14,23); (c) March 2019 - 4 of 31 temperatures were documented as -19 degrees C (Days 13,22,27,31); (d) April 2019 - 7 of 30 temperatures were documented as -19 degrees C (Days 3,6,9,14,18,20,22); (e) May 2019 - 3 of 31 temperatures were documented as -19 degrees C (Days 9,10,11); (f) June 2019 - 2 of 30 temperatures were documented as -19 degrees C (Days 10,16); (g) August 2019 - 1 of 31 temperatures were documented as -19 degrees C (Day 20); (i) September 2019 - 1 of 30 temperatures were documented as -19 degrees C (Day 28); (j) October 2019 - 9 of 31 temperatures were documented as -19 degrees C (Days 2,9,12,23,26,27,28,29,31); (4) The surveyors reviewed the records with the laboratory director and technical supervisor #2/technical consultant #2 who stated the materials had not been stored according to manufacturer's instruction.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director and technical supervisor #2/ technical consultant #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) At the beginning of the survey, the laboratory director stated endocrinology testing was performed on the Immulite 1000 analyzer; (2) Later during the survey, surveyor #2 reviewed the manufacturer's maintenance requirements as stated on page 8-19 of the operator's manual. The requirements for semi- annual maintenance were as follows: (a) Replace the In-Line Filter Tubing (b) Changing the Large Syringe Tip (3) Surveyor #2 then reviewed maintenance records for 10 months (January 2019 through October 2019). The was no evidence the semi-annual maintenance had been performed. (4) The surveyor reviewed the records with the laboratory director and technical supervisor #2/technical consultant #2, who stated the semi-annual maintenance had not been performed as required.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (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 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 a review of records and interview with the technical supervisor#2/technical consultant #2, the laboratory failed to have control procedures that monitored the

	accuracy and precision of the testing process. Findings include: (1) At the beginning of the survey, the technical supervisor#2/technical consultant #2, stated the following to the surveyors: (a) DHEA-S (Dehydroepiandrosterone-sulfate), Estradiol, HCG (Human Chorionic Gonadotropin), FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Prolactin, Testosterone, and TSH (Thyroid Stimulating Hormone) testing were performed using the Beckman Coulter Access 2 analyzer; (b) Three levels of Bio-Rad Liquichek Immunoassay Plus control materials were tested each day that patient testing was performed (the laboratory generally performed the testing on a weekly basis); (c) The laboratory established their own means and ranges before new lot numbers of quality control materials were put into use. (2) Later during the survey, surveyor #1 reviewed quality control records for 6 lot numbers of control materials used during the review period of January 2019 through the day of the survey. For 6 of 6 lot numbers, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances (although the laboratory participated in the Bio-Rad Unity Peer Program, the control results were evaluated against peer data instead of the laboratory established ranges). The QC lot numbers were as follows: (a) Level 1 lot #40951, level 2 lot #40952, and level 3 lot #40953 - In use from 01/01/19 through 08/31/19; (b) Level 1 lot #40991, level 2 lot #40992, and level 3 lot #40993 - Put into use on 09/16/19 and currently in use the day of the survey. (3) Surveyor #1 asked the technical supervisor#2/technical consultant #2 if the lot numbers above had been monitored for variances using the laboratory established ranges. Technical supervisor#2/technical consultant #2 stated to surveyor #1 the controls had not been monitored for variances.