Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2012262	01/16/2024
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 01/16/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, administrative director for regulatory complicance, and technical supervisor #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 director, administrative director for regulatory compliance, and technical supervisor #2, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director and/or testing person(s) for eight of nine events reviewed in 2023. Findings include: (1) A review of 2023 AAB-MLE (American Association of Bioanalysts Medical Laboratory Evaluation) and CAP (College of American Pathologists) proficiency testing records identified the following for eight nine events: (a) AAB-MLE S1 2023 (i) The attestation statement had not been signed by the testing person(s). (b) Y-A 2023 Sex Hormones (i) The attestation statement had not

	been signed by the testing person(s). (c) K-A 2023 Ligand-General (i) The attestation statement had not been signed by the testing person(s). (d) AMH-A 2023 Antimullerian Hormone (i) The attestation statement had not been signed by the testing person(s). (e) Y-B 2023 Sex Hormones (i) The attestation statement had not been signed by the laboratory director and testing person(s). (f) K-B Ligand-General (i) The attestation statement had not been signed by the laboratory director and testing person(s). (g) AMH-B 2023 Antimullerian Hormone (i) The attestation statement had not been signed by the laboratory director and testing person(s). (h) K-C 2023 Ligand-General (i) The attestation statement had not been signed by the laboratory director and testing person(s). (2) The findings were reviewed with the laboratory director, administrative director for regulatory compliance, and technical supervisor #2. All stated on 01/16/2024 at 11:30 am, the attestation statements had not been signed as stated above.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and technical supervisor #2, the laboratory failed to retain quality control records for at least two years for nine of 12 months reviewed from January through December 2023. Findings include: (1) On 01/16/2024 at 09:40 am, technical supervisor #2 stated the following: (a) AMH (Anti-Mullerian Hormone), Estradiol, FSH (Follicle Stimulating Hormone), HCG (Human Chorionic Gonadotropin), DHEA-S (Dehydroepiandosterone Sulfate), FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Prolactin, Testosterone, and TSH (Thyroid Stimulating Hormone) testing were performed on the Beckman Coulter Access 2 analyzer; (b) Three levels (Low, Normal, and High) of Bio-Rad Liquichek AMH Control materials were performed each day of patient AMH testing and three levels (Low, Normal, and High) of Bio-Rad Liquichek Immunoassay Plus Controls were performed each day of patient testing for the remaining analytes. (2) A review of QC (Quality Control) and Levey Jennings records from January through December 2023 identified no evidence that Levey-Jennings graphs and cumulative QC data had been reviewed for nine of 12 months (January through September 2023); (3) Interview with the laboratory director and technical supervisor #2 on 01/16/2024 at 02:00 pm confirmed the following: (a) Levey-Jennings graphs were routinely reviewed and maintained in the analyzer's memory; (b) Due to a hard drive failure, the data had been destroyed prior to October 2023 and was not available for review.
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, written policies and procedures, and interview with the laboratory director, administrative director for regulatory compliance, and technical supervisor #2, the laboratory failed to have a written policy to assess the competency of the general supervisors and technical supervisor, based on the position responsibilities as listed in Subpart M, for six of six persons serving as general supervisor and one of two persons serving as technical supervisor. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the general supervisors and technical supervisor including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of February 2022 through the current date identified competencies, based on job responsibilities, had not been performed for six of six persons listed as general supervisor and one of two persons listed as technical supervisor on Form CMS-209; (3) The findings were reviewed with the laboratory director, administrative director for regulatory compliance, and technical supervisor #2. All stated on 01/16/2024 at 12:10 pm, a policy had not been written and competencies had not been performed for the general supervisors and technical supervisor.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory director and technical supervisor #2, the laboratory failed to follow the manufacturer's instructions for storing patient specimens prior to AMH (Anti-Mullerian Hormone), DHEA-S (Dehydroepiandosterone Sulfate), FSH (Follicle Stimulating Hormone), Prolactin, and Testosterone testing for five of five patient specimens. Findings include: (1) On 01/16/2024 at 09:40 am, technical supervisor #2 stated the following: (a) AMH, DHEA-S, FSH, Prolactin, and Testosterone testing were performed using the Beckman Coulter Access 2 analyzer; (b) Testing for the above analytes was performed each Thursday and aliquoted serum samples were stored in the white LG freezer (denoted by the laboratory as "Endo Freezer 2 (White)). (2) A review of the manufacturer's product inserts for the above analytes identified the following storage requirements under "Specimen Collection and Preparation" for each analyte: (a) For AMH it stated, "If the assay will not be completed within 6 days, or for shipment of samples beyond 6 days, freeze at -20 C or colder"; (b) For DHEA-S, FSH, Prolactin, and Testosterone it stated, "If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 C or colder". (4) Observation of the White LG freezer on 01/16/2024 at 02:45 pm identified the following patient specimens that had been collected from 01/12/2024 through 01/15/2024 awaiting testing: (a) Patient specimen #1 collected on 01/12/2024 for AMH testing; (b) Patient specimen #2 collected on 01/15/2024 for AMH testing; (c) Patient specimen #3 collected on 01/15/2024 for FSH and Testosterone testing; (d) Patient specimen #4 collected on 01/15/2024 for DHEA-S, Prolactin, and Testosterone testing; (e) Patient

	specimen #5 collected on 01/15/2024 for AMH testing. (5) A review of temperature records for January 2024 identified the specimens had been stored at temperatures warmer than -20 degrees C (Centigrade) for five of five days for patient specimen #1 and two of two days for patient specimen #2, patient specimen #3, patient specimen #4, and patient specimen #5 as follows: (a) 01/12/2024 - The documented temperature was -18 degrees C (b) 01/13/2024 - The documented temperature was -19 degrees C (c) 01/14/2024 - The documented temperature was -18 degrees C (d) 01/15/2024 - The documented temperature was -18 degrees C (e) 01/16/2024 - The documented temperature was -17 degrees C (6) The findings were reviewed with the laboratory director and technical supervisor #2. Both stated on 01/16/2024 at 02:55 pm, the patient specimens had not been stored as required by the manufacturer.
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 instructions, observation, and interview with the laboratory director and technical supervisor #2, the laboratory failed to ensure control and calibration materials were stored as required for four of six months during the review period of July 2023 through December 2023 Findings include: (1) On 01/16/2024 at 09:50 am, observation of the contents of the black Frigidaire freezer (a frost-free freezer which was denoted by the laboratory as "Endocrinology Freezer #2), identified the following: (a) Bio-Rad Liquichek Immunoassay Plus Controls - Two boxes of two bottles each of level 1 lot #85331, level 2 lot #85332, and level 3 lot #85333; the storage requirement was -70 to -20 degrees C (Centigrade); (b) Bio-Rad Liquichek AMH Controls - Two boxes of two bottles each of level 1 lot #1001901, level 2 lot #1001902, and level 3 lot #1001903; the storage requirement was -70 to -20 degrees C. In addition, the instructions contained in the package insert stated, "For optimum performance, avoid storing this product in a frost-free freezer"; (c) Access Prolactin Calibrators - Two boxes of lot number 338243; the storage requirement was -20 degrees C and colder; (d) Access Progesterone Calibrators - One box of lot number 338610; the storage requirement was -20 degrees C and colder. (2) A review of temperature records from July 2023 through December 2023 identified documented temperatures were warmer than -20 degrees C (the warmest requirement for the materials above) for four of six months as follows: (a) August 2023 - The documented temperatures were warmer than -20 degrees C for one of 31 days (08/22 /2023); (b) September 2023 - The documented temperatures were warmer than -20 degrees C for three of 30 days (09/17,18,26/2023); (c) October 2023 - The documented temperatures were warmer than -20 degrees C for three of 31 days (10/14, 15,24/2023); (d) December 2023 - The documented temperatures were warmer then -20 degrees C for two of 28 days (12/02,28/2023). (3) The records were reviewed with the laboratory director and technical supervisor #2. Both stated on 01/16/2024 at 12: 45 pm, the materials were not being stored as required by the manufacturer.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, administrative director for regulatory compliance, and technical supervisor #2, the laboratory failed to ensure patient test reports included the name, as stated on the CLIA certificate, and address of the laboratory location where the testing was performed for two of two reports reviewed. Findings include: (1) A review of the following two patient reports identified the laboratory name was listed as "OUHP AELAB-Reproductive Medicine" (the name on the CLIA certificate was "OU Medicine, Inc. Reproductive Health") and the laboratory address was not included: (a) Patient Semen Analysis testing resulted on 01/16/2024; (b) Estradiol, HCG (Human Chorionic Gonadotropin), and Progesterone testing resulted on 01/16/2024. (2) The findings were reviewed with the laboratory director, administrative director for regulatory compliance, and technical supervisor #2. All stated on 01/16/2024 at 01:15 pm, the laboratory name, as stated on the CLIA certificate, and address had not been included on the patient test reports.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the laboratory director, administrative director for regulatory compliance, and technical supervisor #2, the laboratory failed to provide normal reference intervals for one of one patient test report. Findings include: (1) On 01/16/2024 at 09:40 am, technical supervisor #2 stated Estradiol, HCG (Human Chorionic Gonadotropin), and Progesterone testing were performed on the Beckman Coulter Access 2 analyzer; (2) A review of one patient test report for testing performed for the above analytes on 01/16/2024 identified normal reference ranges were not included for each analyte; (3) The report was reviewed with the laboratory director, administrative director for regulatory compliance, and technical supervisor #2. All stated on 01/16/2024 at 01:15 pm the patient report did not include normal reference ranges.