Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2012262	09/24/2025
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 09/23,24/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, general supervisor, patient safety/regulatory manager, medical director, assistant vice president of patient safety/regulatory, director of clinical operations, director of women's services and ambulatory, assistant vice president of laboratory services, and manager of women's services during an exit conference performed at the conclusion of the survey.
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 interview with the laboratory director and general supervisor, the laboratory failed to follow their written policy to assess the competency of the technical supervisor, based on the position responsibilities listed in Subpart M, for one of one person. Findings include: (1) A review of the laboratory policy titled, "Performance Assessment of Supervisors /Consultants" under section III. "Performance Assessment - Technical Proficiency" stated the performance of general and technical supervisors shall be assessed initially (for individuals new to their CLIA role) and annually to determine whether their performance is satisfactory and if they have a continued understanding of their roles and responsibilities"; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of January 2024 through the current date identified competencies, based on job responsibilities, had not been performed prior to 08/09/2025 for one of one

	individual listed as the technical supervisor; (3) The findings were reviewed with the laboratory director and general supervisor who stated on 09/23/2025 at 11:48 am, the policy had not been followed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and general supervisor, the laboratory failed to review and evaluate proficiency testing results for one of four Chemistry proficiency testing events reviewed in 2024 and 2025. Findings include: (1) On 09/23/2025/2025, a review of Chemistry proficiency testing records for 2024 (first, second, and third events) and 2025 (first event) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program) for one of five events: (a) 2025 - CAP Event Y-A (i) Prolactin - five of five results exhibited a positive bias (aa) Sample Y-01 - SDI of 1.9 (bb) Sample Y-02 - SDI of 2.2 (cc) Sample Y-03 - SDI of 2.1 (dd) Sammple Y-04 - SDI of 2.5 (ee) Sample Y-05 - SDI of 2.4 (ii) Testosterone - five of five results exhibited a positive bias (aa) Sample Y-01 - SDI of 1.4 (bb) Sample Y-02 - SDI of 2.6 (cc) Sample Y-03 - SDI of 5.2 (dd) Sample Y-04 - SDI of 2.3 (ee) Sample Y-05 - SDI of 3.0 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with the laboratory director and general supervisor who stated on 09/23/2025 at 01:40 pm, the biases had not been identified and addressed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 written policies and procedures, record review, and interview with the laboratory director and general supervisor, the laboratory failed to follow written procedures, that explained the current practices and procedures being performed in the laboratory for immunoassay quality control for five of five months reviewed. Findings include: (1) On 90/24/2025 at 09:00 am, the general supervisor stated that laboratory performed immunoassay testing using the Beckman Coulter Access II for the following analytes, Estradiol, Progesterone, Human Chorionic Gonadotropin, Luteinizing Hormone, Thyroid Stimulating Hormone, Follicle Stimulating Hormone, Prolactin, Testosterone, High Sensitivity Estradiol, and Anti-Mullerian Hormone; (2) A review of the laboratory's written policy, titled, "Quality Management Program" revealed the following: (a) "Three levels of controls are run on a daily basis, since the laboratory only operates on one eight hour shift per day. Westgard rules will be applied to the collected data to decrease the subjectivity of data analysis and flag results when rules are broken. When controls are out of range,

	controls will be re-run and recalibrated as necessary;" (b) A review of the Accuracy and Precision Flags portion of the Quality Management Policy defines a Westgard 2-2s failure as follows, "Results between 2SD (standard deviation) and 3SD as compared to the previous result. If two consecutive results are greater than 2SD on the same side of the assigned mean, the system:-flags the result as two consecutive controls >2SD (Accuracy) on the QC log report." (3) A review of QC (quality control) and calibration logs from 05/01/2025 through 08/31/2025 identified the following: (a) Estradiol - 2-2s QC failures on 05/04/2025, 05/14/2025, 05/15/2025, 05/16/2025, 05 /20/2025, and 05/21/2025 where no corrective action was documented as performed; (b) Testosterone - 2-2s QC failures on 08/07/2025 and 08/14/2025 where no corrective action was documented as performed; (c) Thyroid Stimulating Hormone - 2-2s QC failures on 07/30/2025 and 07/31/2025 where no corrective action was documented as performed. (4) The records were reviewed with the laboratory director and general supervisor who stated on 09/24/2025 at 9:00 am, the policy was not followed for Westgard 2-2s QC failures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation and interview with the laboratory director and general supervisor, the laboratory failed to ensure four of four packages of Vacutainer blood collection tubes were stored as required by the manufacturer in the storage area located outside the laboratory known as room #228. Findings include: (1) Observation of the storage area located outside the laboratory and interview with the laboratory director and general supervisor on 09/23/2025 at 11:05 am, identified the following: (a) One package of K 2 EDTA Vacutainer blood collection tubes, lot #4330310, storage temperature requirement of 5-25 degrees (C) centigrade; (b) Three packages of SST Vacutainer blood collection tubes, lot #5182941, storage temperature requirement of 5-25 degrees (C) centigrade. (2) Interview with the laboratory director and general supervisor on 09/23/2025 at 11:05 am confirmed the laboratory was not monitoring the temperature of the storage area located outside of the laboratory known as room #228.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 and interview with the laboratory director and general

	supervisor, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Beckman Coulter Access 2 analyzer during the review period of August 2024 through August 2025. Findings include: (1) On 09/23/2025 at 09:40 am, the laboratory director stated the laboratory performed High Sensitivity Estradiol, Estradiol, Progesterone, Human Chorionic Gonadotrophin, Luteinizing Hormone, Thyroid Stimulating Hormone, Follicle Stimulating Hormone, Prolactin, Testosterone, and Anti-Mullerian Hormone testing using the Beckman Coulter Access 2 analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Weekly: (i) Clean Instrument Exterior (ii) Inspect Liquid Waste Bottle (iii) Check Waste Filter Bottle (iv) Inspect/Clean Primary Probes (v) Replace/Clean Aspirate Probes (vi) Inspect Wash Arm Lead Screw Nut Band (vii) Run daily Maintenance (viii) Run System Check (ix) Enter the System Check Results (3) A review of maintenance records from August 2024 through August 2025 identified weekly maintenance had not been documented as performed as follows: (a) Between 08/08/2024 and 08/18 /2024 (b) Between 10/17/2024 and 11/07/2024 - System Check Results not documented in the log (c) Between 11/21/2024 and 12/06/2024 (d) Between 01/02 /2025 and 01/16/2025 (e) Between 02/14/2025 and 02/23/2025 (f) Between 05/15 /2025 and 05/29/2025 (g) Between 07/03/2025 and 07/14/2025 (4) Interview with the laboratory director and general supervisor on 09/23/2025 at 01:48 pm confirmed the maintenance procedures had not been documented as performed as stated above.