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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D2012262 | (X3) Date Survey Completed 01/31/2022 |
| Name of Provider or Supplier Ou Medicine, Inc Reproductive Health | Street Address, City, State 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 |
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| D0000 | The recertification survey was performed on 01/31/2022. The findings were reviewed with the laboratory director, technical supervisor #2, and the general supervisor during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited. |
| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure that proficiency testing samples were tested by personnel who routinely performed patient testing for seven of seven Proficiency Testing events. Findings include: (1) On 01/31/2022 at 10:00 am, the technical supervisor #2 stated the following to surveyor #1: (a) HCG (Human Chorionic Gonadotropin), TSH (Thyroid Stimulating Hormone), DHEA (Dehydroepiandrosterone), Estradiol, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Prolactin, Testosterone, and AMH (Antimullerian Hormone) testing were performed using the Beckman Coulter Access 2 analyzer; (2) Surveyor #2 reviewed the Laboratory Personnel Report (Form CMS-209), that had been completed by the laboratory director prior to the survey. The laboratory director stated that five persons performed the above patient testing in the laboratory (technical supervisor #2/testing person #1, General Supervisor/testing person #2, testing person #3, testing person #4, and testing person #5); (3) Surveyor #2 then reviewed 2021 proficiency testing records and identified that seven of seven events had been tested by the same person (technical supervisor/testing person #1); (4) The findings were reviewed with the laboratory</p> |

director. The laboratory director stated on 01/31/2022 at 12:20 pm, the proficiency testing samples had been tested by technical supervisor/testing person #1, 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, written policy, and interview with the laboratory director, the laboratory failed to have a written general supervisor competency policy based on the position responsibilities as listed in Subpart M for one of one technical consultant. Findings include: (1) On 01/31/2022, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the general supervisor; (2) The surveyor then reviewed personnel records for competency assessments performed during 2020, and 2021. There was no evidence of competencies performed for the general supervisor based on their job responsibilities; (3) The surveyor asked the laboratory director if a written policy to evaluate the general supervisor based on job responsibilities was available. The laboratory director stated on 01/31/2022 at 12:00 pm a policy had not been written and the above competency had not been 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 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; and failed to ensure the humidity of the laboratory was monitored. Findings include: STORAGE OF CONTROL MATERIALS (1) On 01/31/2022 at 10:00 am, surveyor #1 observed the contents of the black Frigidaire freezer in the laboratory (denoted by the laboratory as "Endocrinology Freezer #2), which was a frost-free freezer. The following control materials were being stored in the freezer, with the manufacturer's storage requirements as stated in the package insert: (a) Bio-Rad Liquichek AMH controls - 1 box of 2 bottles each of level 1 lot #48541, level 2 lot #48542, and level 3 lot #48543; the storage requirement was -20 to -70 degrees C (Centigrade). In addition, the instructions contained in the package insert stated, "For optimum performance, avoid storing this product in a frost-free freezer"; (2) On 01/31/2022 at 10:10 am, the laboratory director and technical supervisor #2 stated to surveyor #1 the Bio-Rad

Liquichek AMH controls were used to perform quality control procedures for AMH (Anti-Mullerian Hormone) testing performed on the Beckman Coulter Access 2 analyzer; (3) Surveyor #1 reviewed the manufacturer's instructions with the laboratory director and technical supervisor #2, and explained that the controls were not being stored as required by the manufacturer since they were being stored in a frost-free freezer; (4) The laboratory director and technical supervisor #2 stated to surveyor #1 on 01/31/2022 at 12:00 pm, the controls were not being stored as stated by the manufacturer. STORAGE OF CALIBRATION MATERIALS (1) On 01/31/2022 at 10:20 am, surveyor #1 observed the contents of the white LG freezer, (denoted by the laboratory as Endocrinology Freezer #1), which was a frost-free freezer. the following calibration materials were being stored in the freezer, along with the manufacturer's storage requirements: (a) 1 box of Access Prog Cal, lot #124774; the storage requirement was -20 degrees C and colder; (b) 1 box of Access Prol Cal, lot #124307; the storage requirement was -20 degrees C and colder; (c) 1 box of Access hLH Cal, lot #124361; the storage requirement was -20 degrees C and colder. (2) On 01/31/2022 at 10:30 am, the laboratory director and technical supervisor #2 stated the following to surveyor #1: (a) The refrigerator was new to the laboratory and had been put into use on 01/24/2022; (b) The calibration materials were used for testing performed on the Beckman Coulter Access 2 analyzer as follows: (i) Access Prog Cal was used to perform calibration procedures for Progesterone testing; (ii) Access Prol Cal was used to perform calibration procedures for Prolactin testing; (iii) Access hLH Cal was used to perform calibration procedures for Luteinizing Hormone testing. (3) Surveyor #1 reviewed temperature records for the freezer from 01/24/2022 through 01/31/2022. The documented temperatures were warmer than -20 C (the warmest temperature allowed for the materials) for 2 of 8 days as follows: (a) 01/24/2022 - The documented temperature was -19 C (b) 01/29/2022 - The documented temperature was -19 C (4) Surveyor #1 reviewed the records with the laboratory director and technical supervisor #2. Both stated on 01/31/2022 at 12:05 pm, the freezer temperatures were unacceptable as shown above. HUMIDITY (1) On 01/31/2022 at 10:00 am, the laboratory director and technical supervisor #2 stated to surveyor #1 the laboratory began using the Beckman Coulter Access 2 analyzer to perform HCG (Human Chorionic Gonadotropin), TSH (Thyroid Stimulating Hormone), DHEA (Dehydroepiandrosterone), Estradiol, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Prolactin, Testosterone, and AMH (Antimullerian Hormone) on 04/17/2020; (2) Surveyor #1 reviewed the manufacturer's humidity requirements for the analyzer. The manufacturer required the humidity be maintained at 20-80%; (3) Surveyor #1 asked the laboratory director and technical supervisor #2 if the humidity of the laboratory had been monitored since the analyzer had been put into use. The laboratory director and technical supervisor #2 stated on 01/31/2022 at 02:20 pm the humidity of the laboratory had not been monitored.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

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 ensure the verification data had been evaluated prior to implementing a new analyzer for 1 of 1 new test systems. Findings include: (1) On 01/31/2022 at 10:00 am, the laboratory director and technical supervisor #2 stated to surveyor #1 the laboratory began using the Beckman Coulter Access 2 analyzer to perform HCG (Human Chorionic Gonadotropin), TSH (Thyroid Stimulating Hormone), DHEA (Dehydroepiandrosterone), Estradiol, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Prolactin, Testosterone, and AMH (Antimullerian Hormone) on 04/17/2020; (2) Surveyor #1 reviewed the performance specification records for the new test system and identified that, although the laboratory demonstrated the performance specifications for the test system, there was no evidence the data had been reviewed and evaluated by the laboratory as acceptable; (3) Surveyor #1 reviewed the records with the laboratory director and asked if the laboratory had reviewed and evaluated the data prior to putting the test system into use for patient testing. The laboratory director stated to surveyor #1 on 01/31/2022 at 12:55 pm that, although the laboratory director had reviewed and approved the data prior to beginning patient testing, it had not been documented. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")

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, technical supervisor #2, and the general supervisor, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance procedures for the Beckman Coulter Access 2 analyzer. Findings include: On 01/31/2022 at 10:00 am, the laboratory director and technical supervisor #2 stated to surveyor #1 the laboratory began using the Beckman Coulter Access 2 analyzer to perform HCG (Human Chorionic Gonadotropin), TSH (Thyroid Stimulating Hormone), DHEA (Dehydroepiandrosterone), Estradiol, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Prolactin, Testosterone, and AMH (Antimullerian Hormone) on 04/17/2020; (2) Surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log. The weekly requirements were as follows: (a) Clean Instrument Exterior (b) Inspect Liquid Waste Bottle (c) Check Waste Filter Bottle (d) Inspect/Clean Primary Probe (e) Replace/Clean Aspirate Probes (f) Run System Check (3) Surveyor #1 then reviewed maintenance records from January 2021 through January 2022. The weekly maintenance had not been documented as performed between: (a) 04/15/2021 and 04/26/2021 (b) 06/10/2021 and 06/22/2021 (c) 07/07/2021 and 07/19/2021 (d) 07/19/2021 and 08/05/2021 (e) 12/23/2021 and 01/07/2022 (4) Surveyor #1 reviewed the

findings with the laboratory director, technical supervisor #2, and general supervisor. All stated on 01/31/2022 at 03:00 pm the weekly maintenance had not been documented as performed as identified above.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory director, the laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training. Findings include: (1) On 01/31/2022, surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #3 - This person was hired to perform patient testing on 01/11/2021. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 06/21/2021; (b) Testing #5 - This person was hired to perform patient testing on 11/08/2021. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 12/20/2021; (2) Surveyor #2 reviewed the findings with the laboratory director, who stated on 01/31/2021 at 11:50 am, there was no additional documentation to prove the above person had been initially trained to perform moderate complexity testing.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory director, the laboratory director failed to ensure that a person performing high complexity testing had the appropriate training. Findings include: (1) On 01/31/2022, surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #3 - This person was hired to perform patient testing on 01/11/2021. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 06/21/2021; (b) Testing #5 - This person was hired to perform patient testing on 11/08/2021. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 12/20/2021; (2) Surveyor #2 reviewed the findings with the laboratory director,

who stated on 01/31/2021 at 11:50 am, there was no additional documentation to prove the above person had been initially trained to perform high complexity testing.