Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2270169	03/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ou Health Er & Urgent Care May Avenue	3025 Sw 104th Street, 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 initial survey was performed on 03/18,19/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, regulatory compliance manager, program director, manager of OU Health Community and Outreach laboratories, technical consultant, quality and safety manager, administrative director of OU Health Core, Biochemical, and Community laboratories, and administrative director of OU Health laboratories during an exit conference performed at the conclusion of the survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and interview with the technical consultant and quality and safety manager, the laboratory failed to ensure four of four policies had been approved, signed, and dated by the laboratory director. Findings include: (1) On 03/18 /2024 at 09:40 am, the technical consultant stated the following were performed in the laboratory and IQCP's (Individualized Quality Control Plans), which were effective 08 /17/2023, had been developed for the test systems: (a) PT/INR (Prothrombin Time /International Normalized Ratio) testing using the Hemochron Signature Elite analyzer; (b) Blood Gas (pH, pCO2, pO2), Sodium, Potassium Chloride, Ionized Calcium, Glucose, Lactate, Creatinine, TCO2, and BUN testing using the Siemens EPOC analyzer; (c) BNP (B-Type Natriuretic Peptide) testing using the BNP cartridge and Troponin I testing using cTnI cartridge and the iSTAT 1 analyzer; (d) D-dimer and Urine Drug Screen testing (Triage TOX DS94600) using the Quidel Triage Meter Pro analyzer. (3) A review of the above IQCP's identified the QCP's (Quality Control Plans) for the test systems had not been approved, signed, and dated by the laboratory director; (4) The records were reviewed with the technical consultant and quality and

	safety manager. Both stated on 03/19/2024 at 11:30 am, the QCP's for the above test systems had not been approved, signed, and dated by the laboratory director.
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, and interview with the technical consultant, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the Sysmex XN-330 analyzer for three of three months reviewed in 2023 and 2024. Findings include: (1) On 03/18/2024 at 09:30 am, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Sysmex XN-330 analyzer; (2) A review of the operator's manual for the analyzer required the relative humidity be maintained at 20-85%; (3) A review of laboratory humidity records from December 2023 through February 2024 identified humidity readings were less than 20% for three of three months as follows: (a) December 2023 - Five of 31 humidity readings were documented as less than 20%; (b) January 2024 - 12 of 31 humidity readings were documented as less than 20%; (c) February 2024 - Five of 29 humidity readings were documented as less than 20%. (4) The records were reviewed with the technical consultant who stated on 03/19/2024 at 03:55 pm, the laboratory humidity had not been maintained as required by the manufacturer as shown above.
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 technical consultant and quality and safety manager, the laboratory failed to utilize the demonstrated reportable ranges for two of three new test systems introduced into the laboratory in August 2023. Findings include: iSTAT 1 ANALYZER (1) On 03/18/2024 at 09:20 am, the technical consultant stated the laboratory began using two iSTAT 1 analyzers (Serial Numbers (21)413817 and (21)414064) to perform the following testing on 08/17/2023: (a) BNP (B-Type Natriuretic Peptide) testing using the BNP test cartridge; (b) Troponin I testing using the cTnI test cartridge. (2) A review of the performance specification

	records for the above testing identified the laboratory had demonstrated the following reportable ranges: (a) Serial Number (21)413817 (i) BNP - 92-2746 pg/ml (ii) Troponin I - 0.36-24.94 ng/ml (b) Serial Number (21)414064 (i) BNP - 88-2858 pg/ml (ii) Troponin I - 0.34-25.80 ng/ml (3) Interview with the technical consultant and quality and safety manager on 03/19/2024 at 09:40 am confirmed the laboratory was using the following manufacturer's reportable ranges for both analyzers instead of the reportable ranges that had been demonstrated by the laboratory: (a) BNP - 15-5000 pg /ml (b) Troponin I - 0-50 ng/ml EPOC ANALYZER (1) On 03/18/2024 at 09:30 am, the technical consultant stated the laboratory began using two EPOC analyzers (Serial Numbers 45896 and 45886) to perform Glucose, TCO2, Lactate, and Blood Gas (pCO2, pO2) testing on 08/17/2023; (2) A review of the performance specification records for the analyzers identified the laboratory had demonstrated the following reportable ranges: (a) Serial Number 45896 (i) Glucose - 37-618 mg/dl (ii) TCO2 - 4.5-30.2 mmol/L (iii) Lactate - 0.49-16.83 mmol/L (iv) Blood Gas pCO2 - 2.7-115.7 mm Hg (v) Blood Gas pO2 - 55.5-580.6 mm Hg (b) Serial Number 45886 (i) Glucose - 25-610 mg/dl (ii) TCO2 - 4.6-31.5 mmol/L (iii) Lactate - 0.45-17.35 mmol/L (iv) Blood Gas pCO2 - 2.7-117.5 mm Hg (v) Blood Gas pO2 - 57-597.10 mm Hg (3) Interview with the quality and safety manager on 03/19/2024 at 11:05 am confirmed the laboratory was using the following manufacturer's reportable ranges for both analyzers instead of the reportable ranges that had been demonstrated by the laboratory: (a) Glucose - 20-700 mg/dl (b) TCO2 - 10-50 mmol/L (c) Lactate - 0.3-20 mmol/L (d) Blood Gas pCO2 - 5-150 mm Hg (e) Blood Gas pO2 - 10-750 mm Hg
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 consultant and quality and safety manager, the laboratory failed to ensure data supported the QC (Quality Control) frequency as defined in the IQCP (Individualized Quality Control Plan) for four of four test systems; and failed to perform QC as stated in the IQCP for one of four test systems. Findings include: QUIDEL TRIAGE METER PRO QC DATA (1) On 03/18/2024 at 09:40 am, the technical consultant stated the following: (a) D-dimer and Urine Drug Screen testing (Triage TOX DS94600) were performed using the Quidel Triage Meter Pro analyzer beginning 08/17/2023; (b) IQCP's had been developed for the test systems. (2) A review of the IQCP's (dated as effective 08/17 /2023) identified the QCP's (Quality Control Plan) required two levels of external QC materials be performed each month; (3) A review of supporting documentation for the QCP's identified the following: (a) D-dimer (i) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (ii) Two levels of QC had been tested for three days (not at least 30-31 days). (b) Urine Drug Screen (i) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (ii) Two levels of QC had been tested

	for three days (not at least 30-31 days). (4) The records were reviewed with the technical consultant and quality and safety manager. Both stated on 03/18/2024 at 01: 45 pm, the QC had not been tested to support the QC frequency. ISTAT 1 QC DATA (1) On 03/18/2024 at 09:20 am, the technical consultant stated the following: (a) BNP (B-Type Natriuretic Peptide) testing using the BNP test cartridge and Troponin I testing using the cTnI test cartridge were performed using two iSTAT 1 analyzers (Serial Numbers (21)413817 and (21)414064 beginning 08/17/2023; (b) IQCP's had been developed for the test systems. (2) A review of the IQCP's (dated as effective 08 /17/2023) identified the QCP's required two levels of external QC materials be performed each month; (3) A review of supporting documentation for the QCP's identified the following: (a) BNP (i) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (ii) Two levels of QC had been tested for four days on each analyzer (not at least 30-31 days). (b) Troponin I (i) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (ii) Two levels of QC had been tested for four days on each analyzer (not at least 30 days). (4) The records were reviewed with the quality and safety manager who stated on 03/18/2024 at 02:50 pm, the QC had not been tested to support the QC frequency. EPOC QC DATA (1) On 03 /18/2024 at 09:30 am, the technical consultant stated the following: (a) Blood Gas (pH, pCO2, pO2), Sodium, Potassium Chloride, Ionized Calcium, Glucose, Lactate, Creatinine, TCO2, and BUN testing were performed using the two EPOC analyzers (Serial numbers 45896 and 45886) beginning 08/17/2023; (b) An IQCP had been developed for the test system. (2) A review of the IQCP (dated as effective 08/17 /2023) identified the QCP required two levels of external QC materials be performed each month; (3) A review of supporting documentation for the QCP identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (b) Two levels of QC had been tested for one day on each analyzer (not at least 30-31 days). (4) The records were reviewed with the technical consultant who stated on 03/19/2024 at 11:25 am, the QC had not been tested to support the QC frequency. HEMOCHRON SIGNATURE ELITE QC DATA (1) On 03/18/2024 at 09:40 am, the technical consultant stated the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing were performed using the Hemochron Signature Elite analyzer beginning 08/17/2023; (b) An IQCP had been developed for the test system. (2) A review of the IQCP (dated as effective 08/17/2023) identified the QCP required two levels of external QC materials be performed once per week; (3) A review of supporting documentation for the QCP identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of weekly, as defined in the QCP; (b) Two levels of QC had been tested for five days (not at least seven days). (4) The records were reviewed with the technical consultant who stated on 03/19/2024 at 11:50 am, the QC had not been tested to support the QC frequency. QUALITY CONTROL NOT PERFORMED (1) During the review of QC records for D-dimer and Urine Drug Screen testing peformed on the Quidel Triage Meter Pro analyzer, documentation was not available to prove QC testing had not been performed monthly as stated in the QCP as follows: (a) D-dimer - Not performed between 12/27/2023 and 02/23/2024 (b) Urine Drug Screen- Not performed between 11/15/2023 an 01/30/2024. (2) The records were reviewed with the the technical consultant and quality and safety manager. Both stated on 03/19/2024 at 02:20 pm, QC had not been documented as performed as shown above.
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 technical consultant and quality and safety manager, the laboratory failed to provide therapeutic reference intervals for INR test results for one of one report reviewed. Findings include: (1) On 03/18/2024 at 09:40 am, the technical consultant stated INR-International Normalized Ratio testing was performed using the Hemochron Signature Elite analyzer; (2) A review of one patient report with INR results reported on 02/01/2024 identified the report did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (3) The report was reviewed with the quality and safety manager who stated on 03/19/2024 at 03:45 pm, the patient report did not include a therapeutic range for INR.