Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2270169	10/10/2025
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 recertification survey was performed on 10/09/2025 through 10/10/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the (POC) Point-of-Care Manager, Quality and Safety Manager, Regulatory Accreditation Manager, Program Director, Clinical Manager, Assistant Vice President of Nursing, Human Resource Specialist, Laboratory Operations Director, and Chief of Quality and Safety Officer during an exit conference performed at the conclusion of the survey.
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 policies and procedures and interview with the POC (point-of-Care) manager and Quality and safety manager, the laboratory failed to have a written procedure that reflected the current practices and procedures for one of two procedures reviewed. Findings include: (1) On 10/09/2025 at 12:11 pm, the POC manager stated the laboratory performed i-STAT testing for the following analytes: (a) BNP (B-Type Natriuretic Peptide) test using the BNP cartridge; (b) Troponin I test using the cTnI cartridge. (2) A review of the procedure titled, "i-STAT-1 PORTABLE WHOLE BLOOD CLINICAL ANALYZER SYSTEM - OU HEALTH LABORATORY POINT OF CARE TESTING" stated the following: (a) "The i-STAT-1 Portable Clinical Analyzer provides point of care testing at OU Health for the simultaneous quantitative determination in arterial, venous or capillary whole blood of the following analytes: Crea, cardiac Troponin-I (cTNI), B-type Natriuretic Peptide (BNP), Prothrombin Time (PT), INR and Activated Clotting Time (ACT)." (3)

	Interview with the POC manager and Quality and safety manager 10/10/2025 at 11:25 am confirmed the laboratory did not perform i-STAT testing for the analytes Creatinine, PT/INR, and Activated Clotting Time at the current location and the procedure did not reflect the laboratory's current practices as stated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 interviews with the POC (Point-of-Care) manager, the laboratory failed to utilize the demonstrated reportable ranges for two of two new i-STAT analyzers introduced into the laboratory in June 2025. Findings include: (1) On 10/09/2025 at 12:15 pm, the POC manager stated the laboratory began performing BNP (B-Type Natriuretic Peptide) testing using two new i-STAT analyzers and the BNP cartridge in June 2025; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges for BNP testing: (a) Analyzer Serial #413809 - 14 to 2279 pg/mL; (b) Analyzer Serial #413794 - 15 to 2186 pg/mL. (3) Interview with the POC manager on 10/09/2025 at 03:45 pm confirmed the laboratory was using the manufacturer's reportable range of 15 to 4,492 pg/mL, instead of the reportable ranges that had been demonstrated by the laboratory.