Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656687	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Laboratory Of Oklahoma	1145 S Utica Ave, Suite G-162, Tulsa, 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 11/19,20/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the lab manager, lead tech, quality assurance specialist, director of hospital operations, and the laboratory director during an exit conference performed at the conclusion of the survey.
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 manager, the laboratory failed to review and evaluate proficiency testing results for one of five Chemistry proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 11/19/2024, a review of Chemistry proficiency testing records for 2023 (first, second, and third events) and 2024 (first and second events) 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) CAP C-A 2024 General Chemistry Event (i) Lipase - five of five results exhibited a positive bias (aa) Sample CHM-01 - SDI of 2.6 (bb) Sample CHM-02 - SDI of 2.9 (cc) Sample CHM-03 - SDI of 1.0 (dd) Sample DXH-04 - SDI of 3.7 (ee) Sample DXH-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 manager who stated on 11/19/2024 at 01:40 pm, the biases had not been addressed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory manager, the laboratory failed to ensure Citrol quality control materials had not exceeded their open vial expiration date for two of two vials observed. Findings include: (1) On 11/19 /2024 at 1:30 pm, the laboratory manager stated coagulation testing was performed using the Sysmex CA-600 series analyzer and two levels of Citrol quality control materials were performed each eight hour of patient testing; (2) Observation of the laboratory on 11/19/2024 at 1:30 pm identified two bottles of Citrol quality control material stored refrigerated, without documentation of when they were opened and reconstituted; (3) Review of the manufacturer's storage requirements showed the following: (a) The vials were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The vials were stable refrigerated for 16 hours after reconstitution. (4) Interview with the laboratory manager on 11/19/2024 at 1:30 pm confirmed the Citrol vials had not been dated with the 16 hour expiration date.