Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2247441	08/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ou Health Er & Urgent Care Czech Hall	709 N Czech Hall Rd, Yukon, 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 08/06,07,08/2025 The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief of pathology, vice-chief of pathology services, point of care laboratory manager, laboratory quality and safety manager, regulatory compliance program manager, administrative manager of regulatory compliance, program director of emergency services, laboratory outreach manager, medical director, adult assistant vice president of emergency services, manager of nursing, urgent care and emergency services, director of patient safety, administrative director of regulatory compliance, and the laboratory director 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: I. Based on a review of written policies and procedures, record review, and interview with the laboratory quality and safety manager and the point of care laboratory manager, the laboratory failed to follow written procedures, that explained the current practices and procedures being performed in the laboratory for blood bank alarm checks. Findings include: (1) On 08/07/2025 at 11:00 am, a review of the laboratory's written policy, titled, "ERUC Testing Blood Component Storage Alarms" revealed the alarm checks were to be performed on a quarterly basis; (2) A review of the alarm check records from January 2024, through the current date revealed the following for the alarm checks that had been performed on 03/29/2024, 05/21/2024, 09/27/2024, 12 /20/2024 05/08/2025, 07/30/2025: (a) Alarm checks had not been performed

	quarterly. There was no documentation alarm checks had been performed: (i) Between 12/20/2024 and 05/08/2025. (3) The records were reviewed with the laboratory quality and safety manager and point of care manager who stated on 08/07/2025 at 11: 00 am, the alarm checks had not been performed quarterly.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 point of care laboratory manager, the laboratory failed to ensure iSTAT cartridges had not exceeded their room temperature expiration date for one of two cartridge types observed. Findings include: (1) On 08/06/2025 at 11:30 am, the point of care laboratory manager stated troponin testing was performed using the cTnI cartridge and the iSTAT 1 analyzer; (2) On 08/06/2025 at 11:35 am, observation of the laboratory identified 17 cTnI cartridges stored at room temperature (Lot #E25123), without documentation of when they were removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 14 days. (4) Interview with the point of care laboratory manager 08/06/2025 at 11:42 am confirmed the cartridges had been placed at room temperature without any way to monitor if they exceeded the manufacturer's room temperature expiration date.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory quality and safety manager, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of 45 testing persons. Findings include: (1) On 08/06/2025 at 1130 am, a review of personnel records for one person hired to perform moderate complexity testing after the previous initial survey identified the following for one of four persons reviewed: (a) Testing Person #18 - The initial training was complete on 12/29/23. There was no evidence a competency evaluation had been performed between 12/29 /2023 and 08/19/2024. (2) The records were reviewed with the laboratory quality and safety manager who stated on 08/06/2025 at 11:30 am, a competency evaluation had not been performed semiannually during the first year of testing.