Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0476010	11/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Eastern Oklahoma Medical Center	105 Wall Street, Poteau, 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 10/30/2023 through 11/01/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief nursing officer, chief executive officer, chief operating officer, general supervisor #1 and general supervisor #2 during an exit conference performed at the conclusion of the survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 records, policies and procedures, and interview with general supervisor #1 and general supervisor #2, the laboratory failed to follow their written procedure for CBC (Complete Blood Count) testing for one of five patient reports. Findings include: (1) On 10/30/2023 at 10:20 am, general supervisor #1 and general supervisor #2 stated CBC (Complete Blood Count) testing was performed on the Sysmex XN1000 hematology analyzer; (2) A review of the manual titled, "Laboratory Policy and Procedure Manual" under the hematology procedure, titled, "Manual Differential/Blood Smear Review" stated the following as guidance for when to perform a manual differential or slide review: (a) "For WBC IP Messages: - If there is an Asterisk (*) next to numerical results:" (i) Prepare, stain, and scan a peripheral smear for the presence of any immature, atypical or abnormal cells or clumped platelets; (ii) If NO abnormalities are noted, the instrument results may be reported. A comment must be entered into the LIS that a blood smear was reviewed, and no abnormalities were found; (iii) If abnormalities are noted on the blood smear review, a manual differential will be ordered in the LIS, performed and reported." (3) A review

	of five patient records meeting the criteria for a manual differential or slide review identified no evidence the laboratory followed their written procedure for one of five patient records as follows: (a) Patient tested on 10/27/2023 at 01:03 pm with a WBC IP Message of "Atypical Lympho?" obtained. There was no evidence a blood smear had been reviewed for this flag. (4) The findings were reviewed with general supervisor #1 and general supervisor #2 who stated on 10/31/2023 at 01:50 pm that the procedure had not been followed as indicated above.
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 observation and interview with general supervisor #1, the laboratory failed to ensure four of four types of blood collection tubes were stored as required by the manufacturer, in a room denoted as the supply room. Findings include: (1) Observation of the central supply room and interview with general supervisor #1 on 10 /30/23 at 10:25 am, identified the following: (a) 400 BD Vacutainer EDTA tubes, lot # 31111796, storage temperature of 4-25 degrees Celsius; (b) 300 BD Vacutainer serum tubes, lot # 3123504, storage temperature of 4-25 degrees Celsius; (c) 200 BD Vacutainer lithium heparin tubes, lot # 367884, storage temperature of 4-25 degrees Celsius; (d) 200 BD Vacutainer buffered sodium citrate heparin tubes, lot # 3163627, storage temperature of 4-25 degrees Celsius. (2) Interview with general supervisor #1 on 10/30/2023 at 10:25 am confirmed the laboratory was not monitoring the temperature of the supply room.