Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0901496	01/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
White Eagle Health Center	200 White Eagle Drive, Ponca 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 01/29/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and general supervisor at the conclusion of the survey.
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, observation, and interview with the laboratory director, the laboratory failed to ensure blood collection tubes were stored as required for six of six K2 EDTA tubes. Findings include: (1) On 01/29/2024 at 1:30 pm, observation of the contents of the laboratory refrigerator identified the following materials: (a) Six Vaccuette K2 EDTA 7.2 mg blood collection tubes, lot #454209. (2) Interview with the laboratory manger confirmed the tubes were stored in the refrigerator to utilize when collecting blood samples that required the collection tube to be chilled and sent to the reference laboratory for testing; (3) A review of the manufacturer's storage requirement, which was located on the packaging of unopened containers of blood collection tubes, identified the storage temperature was 4-25 degrees C (Centigrade); (4) The findings were reviewed with the laboratory manager who stated on 01/29 /2024 at 1:30 pm, the blood collection tubes were not being stored as required by the manufacturer.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 general supervisor the laboratory failed to verify the stated value of control materials before they were put into use. Findings include: (1) On 01/29/2024 at 2:00 pm, the general supervisor stated the following: (a) CBC (Complete Blood Count) testing was performed using the Medonic M-series analyzer; (b) Three levels of QC (quality control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records identified no evidence the provided ranges were verified before the lot numbers were put into use since patient testing began on 01/02/2022; (3) Interview with the general supervisor on 01/29/2024 at 2:00 pm. confirmed that the laboratory had not verified the stated value of control materials before new lots of QC had been put into use since patient testing began 01/02/2022.