Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472440	10/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Elkview General Hospital	429 West Elm, Hobart, 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 10/8,9,10,11/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, laboratory manager, and chief executive officer during an exit conference performed at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the laboratory manager, the laboratory failed to establish a written general supervisor competency assessment policy, based on the position responsibilities as listed in the Subpart M. Findings include: (1) A review of written policies and interview with the laboratory director on 10/08/2024 at 02:40 pm identified no evidence of a policy for assessing the competency of a general supervisor; (2) A review of Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of January 2023 through the current date identified no documentation competency assessments had been performed based on position responsibilities for three of three persons listed as general supervisors; (3) The findings were reviewed with the laboratory manager on 10/08/2024 at 02:45 pm, who confirmed the laboratory failed to define and perform assessments based on the specific position responsibilities.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 interview with the laboratory manager, the laboratory failed to utilize the demonstrated reportable range for three of three anaalyes reviewed for the Nova Prime test system. Findings include: (1) On 10/09/2024 at 10:00 am, the laboratory manager stated the laboratory began using the Nova Prime analyzer to perform routine blood gas testing which included the analytes pH, pCO2, and pO2 in September 2024; (2) A review of the performance specifications records identified the laboratory had demonstrated the following reportable ranges for three of three analytes reviewed: (a) pH - 6.674 - 7.784 (b) PCO2 - 7.6 - 137.3 (c) PO2 - 27.4 - 521.1 (3) Interview with the laboratory manager 10/09/2024 at 10:00 am confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) pH - 6.5 - 8.00 (b) pCO2 - 3.0 - 200 (C) pO2 - 5.0 - 765
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory failed to comply with 21 CFR 606.160(b)(3)(v). The laboratory failed to ensure that emergency release of blood forms had been signed by the physician for one of two emergency releases reviewed. Findings include: (1) On 09/09/2024 at 11:00 am, the laboratory manager stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 09/09/2024 a review of the policy titled, "Emergency Blood Transfusion" required an Emergency Release form be completed which stated, "I (last, first) hereby state that this patient (last, first) was in a life or death situation that required that he\she receive blood before it had been crossmatched". The form included a space for the medical provider's signature; (3) A review of documentation of emergency issue identified the following for one of two patient records: (a) One unit of O negative packed red blood cells had been released to a patient on 1/22/2024. The "Emergency Blood Transfusion Form" had not been signed by a physician; (4) The documentation was reviewed with the laboratory manager who stated on 09/09/2024 at 11:00 am, the emergency releases had not been signed by a physician.