

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0648355	(X3) Date Survey Completed 02/21/2024
Name of Provider or Supplier Ellsworth County Medical Center	Street Address, City, State 1604 Aylward Avenue, Ellsworth, KS	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the procedures "Blood Bank Alarm Check (Refrigerator)" and "Calibration Verification Procedure", "Blood Bank Quarterly Alarm Check" log and interview with the technical consultant #2 (TC#2) and general supervisor (GS), the laboratory failed to follow two procedures and failed to perform blood bank alarm checks and six-month calibration/verifications on specific analytes at time of survey. Findings: 1. Review of the procedure "Blood Bank Alarm Check (Refrigerator)" signed by the laboratory director (LD) 02/2024, revealed on page 2 section 6 state: "The sensors should be checked quarterly." a. Review of the "Blood Bank Quarterly Alarm Check" log signed by the LD was only completed once in 2023 on 9/27/2023. No other records could be presented. b. Interview with the GS concurred that the blood bank sensors (Alarm Check) were only performed once in 2023. 2. Review of the procedure "Calibration Verification Procedure" signed by the laboratory director (LD) 02/2024, revealed on page 2 section 3 state: "At least once every 6 months and whenever any of the following occur:" with regards to specific analytes. a. The analyzer, Sysmex EXL and the analytes with less than three calibrators are sodium (Na+), potassium (K+) and chloride (Cl-) did not have six-month calibration /verifications performed. b. There were no records presented at time of survey that proved any calibration/verification were performed on Na+, K+, and Cl- analytes. c. There were approximately 60,000+ patients with Na+, K+ and Cl- analytes performed between 1/1/2023 to 12/31/2023. 3. Interviews with the TC#2 and GS on 2/21/24 at 11:13 a.m. confirmed, the laboratory failed to follow two procedures and did not</p>

perform quarterly blood bank alarm checks and six-month calibration/verifications on specific analytes.