Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450734	10/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Coffey County Hospital Laboratory	801 N 4th Street, Burlington, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the review of the sysmex Dimension EXL (SN 12251151) analyzer calibration verification records for analytes and interview with the Technical Consultant (TC), the laboratory failed to perform calibration verification once every six months on analytes with less than three calibrators at time of survey. Findings: 1. Review of the calibration verification records of the Dimension EXL for the following analytes with less than three calibrators: Sodium (NA), Potassium (K+) and Chloride

	(CL-); revealed the laboratory performed the last six month calibration verification on December 31, 2021, but failed to perform the calibration verification that was due in June 2022. 2. Interview with the TC on October 11, 2022 at 12:24 p.m. confirmed, the laboratory failed to perform calibration verification once every six months on the Dimension EXL with analytes with less than three calibrators.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 review of the laboratory's immunohematology procedures, thermographic temperature charts, daily temperature logs, high/low temperature alarm check records, and interview with technical consultant (TC), the laboratory failed to store immunohematology blood and blood products under appropriate conditions that included the regular inspection of the temperature alarm system at time of survey. Findings: 1. Review of the "Temperature Monitoring Blood Bank Refrigerator" procedure states "The alarm on the refrigerator should be checked periodically for proper functioning." 2. Review of the laboratory's 2021 and to date 10/11/22 thermographic temperature charts and Transfusion Services documents for one blood bank refrigerator showed: a. No identifiers on the thermographic temperature charts to differentiate the "high" and "low" alarms were for performed for the refrigerator that stored packed Red Blood Cells (pRBCs) units. b. The most recent alarm checks for the Blood Bank refrigerator could not be provided at time of survey. c. The TC provided a standard form to be utilized for performing the Blood Bank refrigerator alarm checks, but at time of survey no completed forms could be provided. 7. Interview with TC on October 11, 2022 at 12:04 p.m. the laboratory failed to store immunohematology blood and blood products under appropriate conditions that included the regular inspection of the temperature alarm system at time of survey.