Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441673	10/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Scotland County Hospital	450 E Sigler Ave, Memphis, MO	

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Cell-Dyn Ruby System Operator's Manual, 2021 and to date October 4, 2022 calibration records for the Cell-Dyn Ruby hematology analyzer, and interview with technical supervisor (TS) #2, the laboratory failed to follow manufacturer's recommended frequency of every six months for calibration of the Cell-Dyn Ruby hematology analyzer. Findings: 1. Review of the Cell-Dyn Ruby System Operator's Manual states, "Calibration of the CELL-DYN Ruby may need to be verified in the following instances: At least every six months." 2. Review of 2020, 2021 and to date October 2022 calibration records for the Cell-Dyn Ruby hematology analyzer showed the laboratory failed to perform a calibration for the Cell-Dyn Ruby following manufacturer's recommended frequency of every six months in 2021 and to date October 4, 2022 for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet. 3. Interview with the TS #2 on October 4, 2022 at 11:00 AM confirmed the laboratory failed to follow manufacturer's recommended frequency of every six months for calibration of the Cell-Dyn Ruby hematology analyzer.

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 review of 2021, and to date October 4, 2022 calibration records for the Abbott Architect Plus chemistry analyzer and interview with the technical supervisor (TS) #2, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of Abbott Architect Plus calibration records for 2021, and to date October 4, 2022 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: sodium, potassium, chloride, iron and ferritin. 2. Interview with the TS #2 on October 4, 2022 at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for sodium, potassium, chloride, iron and ferritin.
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 blood bank procedures, "Blood Bank Refrigerator Alarm Chart",

	and interview with the technical supervisor (TS) #2, the laboratory failed to perform blood bank refrigerator alarm inspections according to laboratory's established procedure. Findings: 1. Review of blood bank procedure "BB Temperature Alarm Checks" states "To be completed every 6 months". 2. Review of "Blood Bank Refrigerator Alarm Chart" showed no blood bank alarm check in June 2020, December 2021 and to date October 4, 2022. 3. Interview with the TS #2 on October 4, 2022 at 11:00 AM confirmed the laboratory failed to perform blood bank refrigerator alarm inspections according to laboratory's established procedure.