Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441673	12/01/2020
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of ACL Elite coagulation analyzer, manufacturer's product insert and interview with the general supervisor (GS) the laboratory failed to input correct international sensitivity index (ISI) and normal patient mean for protime (PT) testing used when performing PT tests. One of one patient was reported on December 1, 2020. Findings: 1. Review of ACL Elite coagulation analyzer and manufacturer's product insert, the laboratory failed to input the updated ISI (1.61) and normal patient mean for the new lot of PT reagen in use. Old lot of PT ISI (1.90). Normal patient mean 13.19 2. Review of patient testing showed one of one patient results was reported on December 1, 2020. 3. Interview with the GS on December 1, 2020 at 10: 00 AM, confirmed the laboratory failed to update manufacturer's new ISI and normal patient mean for PT testing.
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 review of temperature charts, manufacturer's package inserts and interview with the general supervisor (GS), the laboratory failed to store Bio-Rad control material according to manufacturer's instructions for 30 of 30 days for the month of November 2020. Findings: 1. Review of Avancto freezer temperature log showed acceptable range of minus 13 degrees to minus 23.8 degrees centigrade. Temperature records showed, the laboratory documented freezer temperature by use of an digital thermometer and a senso temperature monitor. Bio-Rad frozen controls did not reach the required temperature of minus 20 degrees centigrade or colder for the month of November 2020. 2. The manufacturer's package insert states, "Bio-Rad controls are stable when stored at minus 20 degrees to minus 70 degrees centigrade." 3. Interview with the GS on December 1, 2020 at 10:30 AM verified the laboratory failed to properly define the temperature criteria for the Avencto freezer and failed to store frozen Bio-Rad control material consistent with the manufacturer's instructions.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation (logs) for bacteriology and interview with general supervisor (GS), the laboratory failed to check each shipment of blood culture, blood agar and macconkey agar for its ability to support growth and as appropriate, select or inhibit specific organisms. Findings: 1. The lack of QC logs showed the laboratory failed to check each shipment of blood culture, blood agar and macconkey agar for its ability to support growth. 2. Interview with the GS on December 1, 2020 at 10:00 AM confirmed the laboratory failed to check each new shipment of blood culture, blood agar and macconkey agar for its ability to support growth.
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 blood bank procedure manual, lack of blood bank refrigerator alarm records for 2020 and interview with the general supervisor (GS), the laboratory failed to perform and document blood bank refrigerator alarm inspections to ensure blood bank refrigerator temperatures do not exceed the limits of safe storage for blood products as defined in the procedure manual. Findings: 1. Review of the blood bank procedure manual states," temperature alarms need to be tested for activation on a regular basis." The laboratory did not define frequency criteria for regular basis. 2. Review of blood bank refrigerator records for 2020 revealed the laboratory failed to have documentation to show that blood bank refrigerator alarm checks were performed to determine the low and high temperatures that activate the alarm. 3. Interview with the GS on December 1, 2020 at 10:30 AM , confirmed the laboratory failed to have documentation to show inspection of the alarm system for 2020.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the blood bank continuously monitored recording thermograph charts, blood bank temperature log, blood bank policies and interview with general supervisor (GS) the laboratory failed to monitor, assess and correct temperature discrepancies in the blood bank refrigerator for 2020. Findings: 1. Review of recording thermograph charts in the blood bank department from January 1, 2020 to December 1, 2020 showed a consistent temperature of 6.5 degrees Celsius. The blood bank temperature log showed an acceptable range for blood bank refrigerator thermograph charts of 2 to 6 degrees Celsius. 2. Review of the blood bank thermograph temperature log showed the laboratory documented temperatures for the month of November 2020 of 2.9 degrees Celsius to 3.3 degrees Celsius, the actual thermograph recording showed a temperature of 6.5 degrees Celsius. The laboratory failed to ensure correct temperature was documented on the blood bank temperature log from the continuously monitored thermograph charts. 3. Review of laboratory policies state "blood products will be stored in a refrigerator that is monitored and maintained to ensure correct temperature that is documented of 2 to 6 degrees Celsius. Any deviations from the temperature monitoring will be investigated." The laboratory failed to investigate the thermograph chart recording of 6.5 degrees Celsius for the year 2020. 4. Interview with the GS on December 1, 2020 at 11:00, confirmed the blood bank thermograph chart recorder in blood bank was recording incorrect temperature reading from January 1 to December 1, 2020 and the laboratory failed to document actual graph temperature and take corrective actions necessary to resolve the problem.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

	This STANDARD is not met as evidenced by: Based on review of personal records and interview with the general supervisor (GS) the GS failed to have competency records for 1 of 7 testing personnel (TP) for the years 2019 and 2020. Findings: 1. Review of personnel records showed the GS did not have documentation of competency records for TP # 4 for the years 2019 and 2020. 2. Interview with the GS on December 01, 2020 at 11:00 AM confirmed the GS failed to have documentaion of competency records for TP #4 for the years 2019 and 2020.