

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0047626	(X3) Date Survey Completed 05/19/2022
Name of Provider or Supplier Johnson County Hospital	Street Address, City, State 202 High Street, Tecumseh, NE	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory policy, "General Policies for Coagulation", lack of documentation, and interview with the technical consultant and laboratory manager, the laboratory failed to follow manufacturer's instructions and laboratory policy for coagulation. Findings are: 1. Based on the laboratory's policy "General Policies for Coagulation" "with every new lot number of reagents, 20 normal patients will be run to validate the normal range." 2. The laboratory changed innovin lot number and had no documentation of validation of the normal range. 3. Interview with the technical consultant and lab manager on 5/19/2022 at 1pm confirmed the laboratory had changed innovin lot number and had not validated the normal range. 4. The laboratory tested 156 patients since the laboratory changed innovin lot number.</p>