Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0700241	05/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sedan City Hospital	300 North Street, Sedan, 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
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 instrument type and test settings, lack of reagent lot evaluation data, manufacturer's instructions, patient testing volumes and interview, the laboratory failed to follow manufacturer's instruction on reagent lot changes for both Innovin and Actin reagent: prior to use for patient testing. Findings: 1. Prothrombin time (PT) and partial prothrombin time (PTT) testing are performed on the Sysmex CA-660. 2. Sysmex CA-600 instrument setting for PT testing showed Innovin reagent lot #557614A, expiration 10/12/2020. Mean normal patient (MNPT) set at 10.7 seconds, ISI value set at 1.05 and last modification date as 3/13/2021. 3. Review of PT reagent in use found the Innovin reagent lot was #549763, expiration 11/28/2022, ISI value for CA-600 instrument was 1.01. 4. Request was made to review the Innovin reagent lot #549763 evaluation for normal values and NPGM determination. No data was made available at the time of survey. 5. Manufacturer's instructions for Innovin contained " the mean normal PT (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples and, where appropriate, using the coagulation analyzer used for the analysis." 6. Sysmex CA-600 instrument setting for PTT testing showed Actin reagent lot #548460, expiration 1/13/2018. 7. Review of the PTT reagent in use was Actin reagent lot #55766524, expiration 11/30/2023. 8. Request was made to review the Actin reagent lot #55766524 evaluation for normal values. No data was made available at the time of survey. 9. Manufacturer's instructions for Actin contained "Reference intervals vary from laboratory to laboratory depending on the

	population served and the technique, method, equipment and reagent lot used. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed." 10. Review patient test volumes revealed 367 PT and 21 PTT results were reported from 1/14 /2021 to 5/9/2022. 11. Interview with testing personnel (TP) #1 5/9/2022 at 4:30 p.m. confirmed, the laboratory failed to follow manufacturer's instruction on reagent lot changes for both Innovin and Actin reagent: prior to use for patient testing.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 patient transfusion records and interview, the laboratory failed to perform and document a visual inspection/appearance on seven of seven Packed Red Blood Cell (PRBC) units prior to issue for transfusion from 1/14/2020 to 5/9/2022. Findings: 1. Upon review of the blood product issue and transfusion form, there was no designated area for the documentation of a visual inspection of blood product performed immediately before issue. There was also no other entry found on these documents of this inspection. 2. A review of the patient transfusion records revealed seven units of blood were issued for transfusion from 1/14/20 to 5/9/2022. 3. Interview with TP #1 on 5/9/2022 at 1:35 p.m. confirmed, the laboratory failed to perform and document a visual inspection/appearance on seven of seven Packed Red Blood Cell (PRBC) units prior to issue for transfusion from 1/14/2020 to 5/9/2022.