Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453221	06/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hodgeman County Health Center	809 West Bramley St, Jetmore, 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, current reagent lot package insert, current reagent lot evaluation data, and interview, the laboratory failed to follow manufacturer's instructions for the patient normal geometric mean and ISI instrument settings in prothrombin time testing prior to reporting patient results. Findings: 1. Prothrombin time testing is performed on the Sysmex CA-600 using Innovin reagent. 2. Sysmex CA-600 instrument settings for prothombin time testing showed Innovin reagent lot #539338, expiration 1/21/18, ISI setting of 1.00 and normal patient geometric mean set at 10.1 seconds. The last modification date was 3 /16/16. 3. Review of package insert for the current Innovin lot in use at the time of survey was lot #549779, expiration 5/28/23, and an ISI setting of 1.04 for this instrument model. 4. Review of prothrombin time (protime) roll-over data for Innovin lot #549779 performed 10/28/21, defined the normal patient geometric mean as 10.6 seconds. 5. Incorrect normal patient geometric mean values and ISI instrument settings would result in the calculation of an incorrect INR value which may impact patient care. 6. Review of patient data revealed 58 patient results were reported from 10/29/21 to 6/7/22. 7. Interview with General Supervisor (GS) #1 on 6/7/22 at 12:25 p. m. confirmed, the laboratory failed to follow manufacturer's instructions for the patient normal geometric mean and ISI instrument settings in prothrombin time testing prior to reporting patient results.