Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648144	10/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Van Buren County Hospital	304 Franklin Street, Keosauqua, IA	

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) (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 Sysmex CA Series coagulation reagent verification records and confirmed by interview with Technical Supervisor #1 (TS #1) at 2:25 pm on 10/30 /2025, the laboratory failed to verify the manual calculation of the international normalized ratio (INR) for one out of one lot number of prothrombin time reagent (lot number 564677, expiration 12/16/2027). The findings include: 1. The laboratory began using prothrombin time reagent lot number 564677 (expiration 12/16/2027) on 09/17/2025. 2. At the time of the survey, TS #1 confirmed that the laboratory did not perform or document a manual check of the INR calculation from the instrument for prothrombin reagent lot number 564677.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, lack of a quality assessment (QA) policy, and confirmed by interview with Technical Supervisor #1

	(TS #1) at 4:30 pm on 10/30/2025, the laboratory director failed to ensure the establishment and maintenance of a quality assessment program. The findings include: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have a written quality assessment policy that included the four quality systems (general laboratory, pre-analytical, analytical, and post analytical). 2. At the time of the survey, TS #1 confirmed the laboratory did not have a written quality assessment policy.