Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409336	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mckenzie County Healthcare Systems	709 4th Ave Ne, Watford City, ND	

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
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, manufacturer's instructions review, record review, policy review, and staff interview, the laboratory failed to use the correct International Sensitivity Index (ISI) and mean normal protime (PT) values for calculating the International Normalized Ratios (INRs) for 28 of 34 days (2/24-3/21 and 3/26) in 2023 since the laboratory began using a new lot number of Neoplastine (thromboplastin reagent used to analyze protime tests) on their coagulation analyzer on 02/24/23. The laboratory performed approximately 50 tests during this timeframe. Findings include: 1. Observation of the Stago STA Compact MAX coagulation analyzer at 11:55 a.m. on 03/29/23 revealed an ISI of 1.22 and a patient normal mean of 12.9 used to calculate patient INRs. 2. Reviewed at 12:00 p.m. on 03/29/23, the undated STA Neoplastine CI Plus (protime reagent) package insert for lot number 261888 stated the ISI for Stago STA Compact MAX analyzer as 1.22. The document stated, ". . . check that the value taken into account corresponds exactly to that of the reagents being used." 3. Reviewed at 12:05 p.m. on 03/29/23, the laboratory's records for validation of Neoplastine lot number 261888, dated February 2023, revealed a patient normal mean of 13.0. 4. Reviewed on 03/29/23, the manufacturer's instructions for STA Neoplastine CI Plus, dated May 2019, stated, ". . . 2/ Summary and Explanation . . . The PT is commonly used for monitoring vitamin K antagonist therapy . . . It is well known that the PT value of a plasma may vary according to the origin of the thromboplastin reagent and to the instrument used to measure it. . . . the PT ratio is converted into the International Normalized Ratio (INR). The INR value corresponds to the value of the ratio of the patient's PT to that of the standard PT raised to the ISI (International Sensitivity Index) power of the thromboplastin used. . .

	. 5. Reviewed on 03/29/23, the policy "Stago-Neoplastine - Determination of Prothrombin Time (PT)," effective 07/01/18, stated, ". . . Reference Interval . . . If PT-INRs are reported, a lot specific ISI value and Reference Time or geometric mean must be entered into the instrument. . . . in order for the correct calculation of the INR. . . ." 6. Reviewed at 3:00 p.m. on 03/29/23, the STA Compact MAX maintenance records from 02/24/23 through 03/28/29 showed the following documentation of the ISI and patient normal mean programmed into the analyzer: - 02/24/23 through 03/21 /23: ISI 1.28 and patient normal mean 12.9 (values from the previous lot number of Neoplastine). - 03/26/23: patient normal mean 12.9 (value from the previous lot number of Neoplastine). 7. During interview at 12:15 p.m. on 03/29/23, a technical supervisor (#1) stated the laboratory began using a new lot number of Neoplastine reagent on 02/24/23 and confirmed the patient normal mean entered into the analyzer was incorrect on 03/29/23 at 11:55 a.m. During interview at 3:00 p.m. on 03/29/23, a technical supervisor (#1) confirmed the laboratory's documentation of the coagulation analyzer's ISI and patient normal mean values showed incorrect values from 02/24/23 through 03/21/23 and an incorrect patient normal mean on 03/26/23.