Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0516830	07/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sedgwick County Health Center	900 Cedar St, Julesburg, CO	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and an interview with the general supervisor (GS), the laboratory failed to replace the Siemens Dade Innovin reagent after it had exceeded the expiration date and approximately 50 PT/INR patient tests had been performed using this reagent. Findings include: 1. An observation of the laboratory's reagents on July 22, 2024, at approximately 12:15 PM, revealed five vials of Siemens Dade Innovin reagent, lot number: 5497941C, expired on: 1/14/2024. 2. An interview with the GS on July 22, 2024, at approximately 12:20 PM, confirmed that the Siemens Dade Innovin reagent had expired and had been used for PT/INR testing for approximately 50 patients.
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 the laboratory's policies and procedures manual, and an interview

	with the General Supervisor (GS), the laboratory failed to establish a policy or procedure for determining the criteria for whether returned blood is suitable for reissue, and for the visual inspection of red blood cells immediately before distribution since the last survey was conducted on November 5, 2021. The laboratory performs approximately 186 immunohematology tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure for determining the criteria for whether returned blood is suitable for reissue since the last survey was conducted on November 5, 2021. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure for the visual inspection of red blood cells immediately before distribution since the last survey was conducted on November 5, 2021. 3. The laboratory performs approximately 186 immunohematology tests annually. 4. Based on an interview with the GS on July 22, 2024, at approximately 12:45 PM, confirmed that the laboratory failed to establish a policy or procedure for determining the criteria for whether returned blood is suitable for reissue, and for the visual inspection of red blood cells immediately before distribution.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to document their quarterly alarm check for their temperature monitoring system attached to their blood product storage refrigerator and freezer since the last survey was conducted on November 5, 2021. The laboratory conducts approximately 186 immunohematology tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, revealed the laboratory failed to follow their policy and procedure for documenting quarterly alarm checks for their temperature monitoring system attached to their blood product storage refrigerator and freezer since the last survey was conducted on November 5, 2021. 2. Based on an interview with the GS on July 22, 2024, at approximately 12:25 PM, confirmed that the laboratory had failed to document their quarterly alarm checks of the temperature monitoring system attached to their blood product storage refrigerator and freezer since the last survey was conducted on November 5, 2021.