Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0516938	04/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lincoln County Community Hospital	111 6th St, Hugo, 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
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. 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 establish a written policy or procedure to ensure the storage conditions of blood products are appropriate to prevent deterioration of the products during a failure of the laboratory's monitored refrigerator since the laboratory's last survey was conducted on 11/08/2021. The laboratory performs approximately 190 immunohematology tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, revealed the laboratory failed to establish a written policy or procedure to document and monitor the temperature of blood products to prevent the deterioration of blood products in case of a failure of their monitored refrigerator since the last survey was conducted on 11/08/2021. 2. An interview with the GS on April 11, 2024, at approximately 12:15 PM, confirmed that the laboratory failed to establish a written policy or procedure to document and monitor the temperature of blood products to prevent the deterioration of blood products in case of a failure of their monitored refrigerator.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance

	(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, proficiency testing (PT) records review, and an interview with the general supervisor (GS), the laboratory failed to establish a written policy or procedure for, and failed to evaluate PT results that were not evaluated or scored by the PT provider since the laboratory's last survey on 11/08/2021. The laboratory performs approximately 122,117 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory failed to establish a written policy or procedure for evaluating PT scores that were not evaluated or scored by the PT provider since the last survey was conducted on 11/08/2021. 2. A review of the laboratory's PT records revealed the laboratory did not evaluate the accuracy of any analyte for which the PT provider did not evaluate or score since the last survey was conducted on 11/08/2021. 3. An interview with the GS on April 11, 2024, at approximately 12:00 PM, confirmed that the laboratory failed to establish a written policy or procedure for, and evaluate any PT scores that the PT provider did not evaluate or score since the laboratory's last survey was conducted on 11/08/2021.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, and an interview with the general supervisor (GS), the laboratory failed to establish a written policy or procedure for a quality assurance (QA) plan, establishing an ongoing mechanism to monitor, assess and correct problems when indicated, concerning: patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance since the last survey was conducted on 11/08/2021. The laboratory laboratory performs approximately 122,117 tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual revealed the laboratory failed to have a written policy or procedure for a QA plan establishing an ongoing mechanism to monitor, assess and correct problems when indicated, concerning: patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance since the last survey was conducted on 11/08/2021. 2. Based on an interview with the GS on April 11, 2024, at approximately 11:30 AM, confirmed that the laboratory failed to have a written policy or procedure for a QA plan establishing an ongoing mechanism to monitor, assess and correct problems when indicated, concerning: patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance since the last survey was conducted on 11/08/2021.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. 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 director (LD) failed to ensure that the laboratory's policies and procedures manual for chemistry, hematology, blood bank, and microbiology had been approved, signed, and dated by the current LD before use since the laboratory's last survey on 11/08/2021. The laboratory performs approximately 122,117 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual for chemistry, hematology, blood bank, and microbiology revealed that the current LD had not approved, signed, or dated the laboratory's policies and procedures prior to their use in the laboratory. 2. Based on an interview with the GS on April 11, 2024, at approximately 11:45 AM, confirmed that the current LD had not reviewed, signed, and dated the laboratory's policies and procedures manual for chemistry, hematology, blood bank, and microbiology prior to their use in the laboratory.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on an onsite records review, a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to compare, or establish a policy or procedure to compare their Sysmex Hematology analyzer's automated white blood cell (WBC) differential at least semiannually to their manual WBC differential since the laboratory's last survey on 11/08/2021. The laboratory conducts approximately 8,443 hematology tests annually. Findings include: 1. Based on an onsite records review, the laboratory failed to compare the automated WBC differential obtained on their Sysmex Hematology analyzer to the results obtained using manual WBC differentials at least semiannually. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure to compare the automated WBC differential obtained on their Sysmex Hematology analyzer to the results obtained using manual WBC differentials at least semiannually. 3. Based on an interview with the GS on April 11, 2024, at approximately 1:00 PM, confirmed that the laboratory failed to compare and establish a policy or procedure to compare the automated WBC differential obtained on their Sysmex Hematology analyzer to the results obtained using manual WBC differentials at least semiannually.