Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409361	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Stillwater Billings Clinic	710 N 11th Street, Columbus, MT	

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 review of Immunohematology records, policy and procedure, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and unused blood or blood products returned to the laboratory for years 2020 and 2021. Findings: 1. Review of Immunohematology records lacked documentation of temperatures of blood and blood products upon receipt of new shipments and unused blood or blood products returned to the laboratory for years 2020 and 2021. 2. No procedure for receipt of incoming blood products was available for review. 3. Review of Policy and Procedure Lab-158, Criteria for Return of Unused Blood lacks temperature requirements for acceptance of blood or blood products not used for transfusion. 4. Interview with TS #1 on January 12, 2022 at 12:00 PM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and of unused blood or blood products returned to the laboratory for years 2020 and 2021.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on Immunohematology's record review, policy and procedures, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure written procedures were followed for documenting the return of unused blood product and/or samples of each unit of transfused blood. Findings: 1. Review of Policy and Procedure Lab-158, Criteria for Return of Unused Blood states "2. Indicate on the Transfusion Service Record that the blood was returned and note the time." 2. Review of Transfusion Service Record lacked documentation of returned samples for each unit of transfused blood for blood products issued 3/9/2020, 7/27/2020, 7/28/2020, 8/25/2020, 9/28 /2020, 3/31/2021, and 4/7/2021. 3. Interview with TS #1 on January 12, 2022 at 12:15 PM, confirmed the laboratory failed to ensure written procedures were followed for documenting the return of unused blood product and/or samples of each unit of transfused blood.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review of Immunohematology, policy and procedures, and interview with Technical Supervisor (TS) #1, the laboratory failed to identify and correct problems and prevent their recurrence for Immunohematology's lack of documentation of returned samples for each unit of transfused blood for blood products on the Transfusion Service Record. Findings: 1. Review of Transfusion Service Record lacked documentation of returned samples for each unit of transfused blood for blood products issued 3/9/2020, 7/27/2020, 7/28/2020, 8/25/2020, 9/28 /2020, 3/31/2021, and 4/7/2021. (Cross refer D5401) 2. Review of Policy and Procedure, Lab-154 Blood Bank Quality Assurance revealed, "8. Weekly review of the Blood Bank charts, Blood Bank inventory, and temperature logs by an assigned technologist." 3. No corrective action or remedial training records were available for review regarding the missing documentation on the Transfusion Service Record. 4. Interview with TS #1 on January 12, 2022 at 12:20 PM, confirmed the laboratory failed to identify and correct problems and prevent their recurrence for Immunohematology's lack of documentation of returned samples for each unit of transfused blood for blood products on the Transfusion Service Record.