Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2265176	03/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Billings Clinic Bozeman	3905 Wellness Way, Bozeman, 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
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) (a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. This STANDARD is not met as evidenced by: Based on a record review and interview with General Supervisor (GS) #1, the laboratory lacked an approved agreement for transfusion services between three of three facilities to determine which services are provided directly by the facility and which are provided by the agreement and ensure the agreement is being met from March 12, 2023, to March 12, 2025. Findings: 1. A review of the laboratory's policies and procedures lacked the following: An approved agreement between three facilities, one facility (vendor) providing the blood products, one facility providing the blood typing and one facility storing and transfusing the blood products. A written step-by-step process to determine which services are provided by each facility. 2. An interview with GS #1 on March 12, 2025, at 12:40 PM confirmed that the laboratory failed to have an approved written transfusion service agreement and step-by step procedure to outline which services are provided by each facility from March 12, 2023, to March 12, 2025.
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) (a)(3)(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

	This STANDARD is not met as evidenced by: Based on observation, record review and interview with General Supervisor (GS) #1, the laboratory failed to perform and document daily visual checks of the blood bank inventory for five out of five red blood cells (RBCs) units during storage and failed to retrieve transfusion records for six out of six red blood cells (RBCs) units transfused from March 12, 2023, to March 12, 2025. Findings: 1. Observed on March 12, 2025, at 12:20 PM one Helmer iBX020 HaemoBank (Trademark) 20 refrigerator containing 5 units of RBCs (one A Rhesus (Rh) factor positive, one A Rh negative, two O Rh positive, one O Rh negative) ready for use. 2. A review of BB-192 log for blood product storage lacked documentation of daily visual inspections of blood products during storage. 3. A review of transfusion records revealed staff failed to provide records that the RBCs unit type was verified, and the patients' blood samples were compatible for the following units transfused: W0423230289203, W042324004893J, W042324011033C, W0423240123603, W042324023294H, W0423240183754. 4. An interview with GS #1 on March 12, 2025, at 12:35 PM confirmed the lack of daily visual inspection of their RBCs units during storage and failed to retrieve transfusion records for six out of six red blood cells (RBCs) units transfused from March 12, 2023, to March 12, 2025.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 a record review and interview with the General Supervisor (GS) #1, the laboratory failed to provide the manufacturer's user manuals for their Helmer iBX020 HaemoBank 20 refrigerator, Helmer iBR105-GX refrigerators, and BloodTrack software and failed to have a procedure for tracking records of transfused patients using their laboratory information system from March 12, 2023, to March 12, 2025. Findings: 1. A review of the laboratory's policies and procedures lacked a process for traceability of transfused patients using their laboratory information system (PathNet software). (Cross refer D3035) 2. The laboratory failed to have available the manufacturer's user manuals for their Helmer iBX020 HaemoBank 20 refrigerator, Helmer iBR105-GX refrigerator, and BloodTrack software at the time of the survey. 3. An interview with GS #1 on March 12, 2025, at 12:50 PM confirmed the lack of two Helmer refrigerators and BloodTrack software user manuals and a procedure for tracking records of transfused patients using their laboratory information system from March 12, 2023, to March 12, 2025.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information

	regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with General Supervisor (GS) #1, the laboratory failed to provide in its patient's results report for prostate-specific antigen (PSA) the test method used from March 12, 2023, to March 12, 2025. Findings: 1. A review of patient's results report for PSA lacked the test method used listed in the report. 2. An interview with GS #1 on March 12, 2025, at 4:00 PM confirmed the patient's results report failed to list the test method used for PSA from March 12, 2023, to March 12, 2025.