Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410733	02/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Barrett Hospital & Healthcare Laboratory	600 Mt Highway 91 South, Dillon, 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 returned blood and blood products not used for transfusion from January 1, 2020 to February 2, 2022 Findings: 1. Review of Immunohematology records lacked documentation of temperatures for blood and blood products upon receipt of new shipments and for unused blood or blood products returned to the laboratory from January 1, 2020 to February 2, 2022. 2. Review of Receiving, Sending, and Retesting Blood Products procedure lacks temperature requirements for acceptance of blood and and blood products. 3. Review of Emergency Release of Blood procedure revealed "3(a)(ii). The blood must not have been allowed to warm above 10 degrees C or cool below 1 degree C during storage or transport." 3. Interview with TS #1 on February 2, 2022 at 1:00 PM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and returned blood or blood products not used for transfusion from January 1, 2020 to February 2, 2022
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the hematology records, policy and procedures and interview with technical supervisor (TS) #1, the laboratory failed to include in their procedure manuals a step-by-step procedure for the preparation of blood smears for manual differentials, associated reference intervals (normal values), and the intended staining characteristics for manual differentials stained with the Aerospray Stat Slide Stainer. Findings: 1. No step-by-step procedure for the preparation of blood smear for manual differential with associated reference intervals (normal values) was available for review. 2. Review of hematology records revealed the laboratory failed to document the staining quality of manual differential slides each day of staining with the Aerospray Stat Slide Stainer from January 1, 2020 to February 2, 2022. 3. Interview on February 2, 2022 at 11:00 AM with the TS #1, confirmed the laboratory failed to include in their procedure manuals a step-by-step procedure for the preparation of blood smears for manual differentials, associated reference intervals (normal values), and the intended staining characteristics for manual differentials stained with the Aerospray Stat Slide Stainer.
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 of Immunohematology's lack of documentation for emergency release of blood and blood products and the return of unused blood or blood products on the Transfusion Service Record for 1/27/2020, and 1/6/2021. Findings: 1. Review of Transfusion Service Record lacked record of date, time, visual inspection and issued to of emergency release blood or blood product issued, and date, time, visual inspection and technologist of unused blood or blood product returned to

	the laboratory on 1/27/2020, and 1/6/2021. 2. Review of Emergency Release of Blood states "3(a)(iii). The records must indicate that the blood has been reissued and inspected prior to reissue. Document the time/date of return by the sign-out date/time in the Blood Bank Log." 3. No corrective action or remedial training records were available for review regarding the missing information on the Transfusion Service Record. 4. Interview with TS #1 on February 2, 2022 at 1:20 PM, confirmed the laboratory failed to identify and correct problems and prevent their recurrence for Immunohematology's lack of documentation for emergency release of blood and blood products and the return of unused blood or blood products on the Transfusion Service Record for 1/27/2020, and 1/6/2021.