Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409444	09/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Beartooth Billings Clinic	2525 North Broadway, Red Lodge, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of records, policy, and interview with General Supervisor (GS) #1, the laboratory failed to establish a written quality assurance (QA) policy to outline an ongoing mechanism to monitor, assess and correct problems in the laboratory from April 14, 2021 to September 21, 2022. Findings: 1. No quality assurance policy to cover the laboratory's preanalytical, analytical and post analytical systems was available for review. 2. Review of Quality Improvement Activities/Calendar revealed, "BC is fixing the Cerner TAT monitor" documented since 2018 with no resolution. 3. Review of Quality Improvement Activities/Calendar lacked assessment of the analytical system for test procedures; specimen and reagent storage condition; maintenance and function checks; establishment and verification of method performance specifications; calibration and calibration verification; control procedures; comparison of test results; corrective actions; and test records. Cross refer (D5792) 4. Interview with GS #1 on September 21, 2022, at 3:00PM, confirmed these findings.
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 review of Immunohematology's records, policies, and interview with General Supervisor (GS) #1, the laboratory failed to identify and correct problems and prevent their recurrence for Immunohematology's lack of documentation as required by their policies and worksheets for six out of 12 patients transfused from April 5, 2021, to August 29, 2022. Findings: 1. Review of policy, "Issuing of Blood Products" revealed, "Patient name on the blood bank log matches the patient name on the blood unit sticker."; "The donor unit number on the blood matches the unit number on the blood unit sticker on both the unit and the blood bank logbook." and the "Visual Inspection", "Issued By", "Inspected By", "Date/Time" and "Issued To" are to be completed in the blood bank logbook. 2. Review of Emergency Transfusion of Blood policy revealed, "4. RN and witness must sign out Blood unit on the blood bank log." 3. Review of blood bank records revealed the following: a. Blood Bank Transfusion Work Sheets for two different patients, dated 10/15/2021 and 10/17/2021 were labeled with the same transfusion number - ELHB 7257. b. Blood Bank Transfusion Work Sheet lacked entry for either patient name, Acct #, Form Prepared by, or unit Donor Number for dates 10/15/2021 and 10/29/2021. c. No Blood Bank Transfusion Work Sheet for ELHB 4494 for 4/21/2022 was available for review. d. Transfusion Service Testing Record entry for 5/14/2022 lacked donor unit number - W042322005750 and transfusion number - ELH 4393. e. Transfusion Service Testing Record entry for 06/23 /2021 lacked documentation for component, issued by, visual inspection, issued to and date/time for two units issued as indicated on the Emergency Transfusion request for transfusion number ELHB 7067. 4. No corrective action or remedial training records were available for review regarding the missing documentation on the Immunohematology records. 5. No quality assessment policy was available for review. Cross Refer (D5791) 5. Emergency Transfusion Request and Blood Bank Transfusion Work Sheet documents lacked review by the laboratory director. 6. Interview with GS #1 on September 21, 2022, at 9:00 AM, confirmed the laboratory failed to identify and correct problems and prevent their recurrence for Immunohematology's lack of documentation.