Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0671192	09/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clark Fork Valley Hospital	10 Krueger Road, Plains, 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 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 of 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 of blood or blood products returned to the laboratory for years 2020 and 2021. 2. Review of PolicyStat ID: 10184766; Receipt of Incoming Blood Products revealed, "The receiving tech must: assure that the shipping container is intact, observe the shipment temperature and report unacceptable finding to the shipping facility, inspect each unit for abnormal appearance...storage".. 3. Review of logbook, Unit # W202021478858 for emergency release dated 9/25/2021 @ 1830 revealed unused units returned on ice at 9/26/2021 @ 2330." 4. No temperature documents for receipt of blood and blood products was available for review. 5. Interview with TS #1 on September 28, 2021 at 1:10 PM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and of blood or blood products returned to the laboratory for years 2020 and 2021.
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, urinalysis, chemistry, arterial blood gas, and interview with Technical Supervisor (TS) #1, the laboratory failed to include in their procedure manuals reference intervals (normal values) for complete blood counts, lipid panel, comprehensive metabolic panel, microscopic urinalysis, and arterial blood gas. Findings: 1. No reference intervals (normal values) were available in the hematology procedure manual for complete blood counts. 2. No reference intervals (normal values) were available in the urinalysis procedure manual for microscopic urinalysis. 3. No reference intervals (normal values) were available in the chemistry procedure manual for comprehensive metabolic panel and lipid panel. 4. No reference intervals (normal values) were available in the arterial blood gas procedure. 5. Interview with the TS #1 on September 28, 2021 at 11:00 AM confirmed the laboratory failed to include normal values for complete blood counts, lipid panel, comprehensive metabolic panel, microscopic urinalysis, and arterial blood gas procedure manuals.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review of Blood Banking and interview with Technical Supervisor (TS) #1, the laboratory failed to consistently document the visual inspection of blood and blood products upon receipt of new shipments and return of blood or blood products to be transfused for 2021. Findings: 1. Review of Blood Banking packing slips from 9/8/2021 to 9/27/2021 revealed three of five lacked documentation of visual inspection upon receipt of blood and blood products. 2. Review of PolicyStat ID: 10184766; Receipt of Incoming Blood Products revealed, "The receiving tech

	must: assure that the shipping container is intact, observe the shipment temperature and report unacceptable finding to the shipping facility, inspect each unit for abnormal appearance...storage". 3. Review of logbook, Unit # W202021478858 for emergency release dated 9/25/2021 @ 1830 revealed unused units returned on ice at 9/26/2021 @ 2330." No visual inspection was recorded. 4. Interview with TS #1 on September 28, 2021 at 1:15 PM, confirmed the laboratory failed to consistently document visual inspection of blood and blood products upon receipt of new shipments and return of blood and blood products to be transfused for 2021.