

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410425	(X3) Date Survey Completed 05/18/2022
Name of Provider or Supplier Billings Clinic Broadwater	Street Address, City, State 110 North Oak Street, Townsend, 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	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Immunohematology records, procedure, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood products and of returned/reissued blood products not used for transfusion from January 1, 2020 to May 18, 2022. Findings: 1. Review of Blood Product Receiving and Distribution Log revealed "Date Rec'd; Rec'd Temp" column with no temperature recorded. 2. Immunohematology records lacked documentation of temperatures of blood products reissued to the laboratory from January 1, 2020 to May 18, 2022. 3. Review of Manual Blood Bank Procedures revealed, "To ensure that all regional hospital blood banks receive blood products that are of the highest quality and safe for transfusion, the American Red Cross requires all of its Blood Centers to monitor the temperature of blood products shipped to participating hospitals". 4. Interview with TS #1 on May 18, 2022 at 12:30 PM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood products and returned/reissued blood products not used for transfusion from January 1, 2020 to May 18, 2022</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)</p>

Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on coagulation record review, procedure, and interview with Technical Supervisor (TS) #1 and #2, the laboratory failed to establish and follow written policies and procedures for accessioning of prothrombin time (PT) and international normalized ratio (INR) test requests and collection of the appropriate specimen for 8 out of 27 patients in June, July, and August of 2021. Findings: 1. Review of Coagulation (Sysmex CA 600) patient results report (#21-208-0580) revealed PT/INR results were verified and released on 7/27/2021 at 6:25AM 2. Review of the Sysmex CA-600 Operator's Maintenance checklist revealed no testing was performed on 7/27/2021. 3. Review of CoaguCheck Patient Log revealed the following patients' orders for the Sysmex CA 600 were incorrectly performed on the CoaguCheck: a. On 6/16/2021 patient accession #21-167-1958 and #21-167-1910 b. On 7/27/2021 patient accession #21-208-2164 and #21-208-0580 c. On 7/25/2021 patient accession #21-206-0465 d. On 7/23/2021 patient accession #21-204-2956 and #21-204-0632 e. On 8/7/2021 patient accession #21-219-0600 4. Review of Sysmex Instructions for use CA 600 series revealed, "5.10 Prepare Plasma. 1) Add 1 part of 3.8%, 3.2% or 3.13% sodium citrate solution as anticoagulant to 9 parts of venous blood, and mix the contents thoroughly." 5. Review of CoaguCheck XS PT Test package insert revealed, "Limitations of procedure: The CoaguCheck XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used." 6. No policy and procedure for coagulation ordering instructions was available for review at the time of the survey. 7. Interview with the TS #1 and TS #2 on May 18, 2022, at 3:40 PM confirmed these findings.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on record review, procedures, and interview with Technical Supervisor (TS) #1 and #2, the laboratory failed to establish and follow written policies and procedures for its review of its quality assurance program from January 1, 2021 to May 18, 2022. Findings: 1. Review of Quality Assurance Program procedure revealed, "Quality Control Assessment, a) Problems identified during evaluation of calibration and control data for each test method." 2. Review of CoaguCheck Patient log lacked quality control assessment review by technical supervisor or laboratory director for June, July, August, November and December of 2021. 3. Review of Coagulation Worksheet PT PTT lacked quality control assessment review by technical supervisor or laboratory director for October, November and December of 2021. 4. No corrective action reports for missed calibration verifications studies for chemistry electrolytes and blood gas were available for review for year 2021. 5. Review of Quality Assurance Program procedure revealed, "Comprehensive QA Program: Evaluate effectiveness of its policies and procedures; Identify and correct problems; Assure the

accurate, reliable and prompt reporting of the results." 6. No review process of the effectiveness of the laboratories policies and procedures, including IQCP were available for review for 2021. 7. No Random Chart Review or amended patient results reports for incorrect coagulation orders were available for review for year 2021. 8. Interview with TS # 1 and TS # 2 on May 18, 2021, at 4:30 PM, confirmed these findings. See (D5311)