

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0665300	<b>(X3) Date Survey Completed</b>  10/02/2024
<b>Name of Provider or Supplier</b>  Livingston Healthcare	<b>Street Address, City, State</b>  320 Alpenglow Lane, Livingston, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5553</b>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f)</p> <p>(b) Immuno-hematological 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of immuno-hematology records, policies, and interview with technical supervisor (TS) #1, the laboratory failed to include the physician's signature for the emergency issuance of four out of four blood units released on February 2, 2024, and June 12, 2024, and failed to document the temperature of seven out of seven blood units reissued from April 10, 2023, to February 27, 2024. Findings: 1. A review of "Blood Bank Transfusion Records" used to record uncrossmatched blood units transfused failed to include the physicians' signature for the emergency issuance of three blood products released on June 12, 2024 (visit #770470020) and one blood product released on February 2, 2024 (visit #770498902) as required by their Emergency Issuance of Blood Products policy. 2. A review of immuno-hematology records revealed the laboratory failed to take and record the temperature of units not transfused and reissued for service on 4/10/2023 (unit W042323007004), 9/5/2023 (units W042423114692, W042423115731), 12/25/2023 (units W042323026673, W042323028619), and 2/27/24 (units WO04232400464, W042324003012) as required by their Emergency Issuance of Blood Products policy. 3. An interview with TS #1 on October 1, 2024, at 12:00 PM confirmed emergency release documents did not include the physicians' signature, and laboratory staff failed to take and record the temperature of reissued blood products per their policy from April 10, 2023, to February 27, 2024.</p>