

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 27D0652478	<b>(X3) Date Survey Completed</b> 05/13/2021
<b>Name of Provider or Supplier</b> Roosevelt Medical Center	<b>Street Address, City, State</b> 818 2nd Avenue East, Culbertson, 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>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory records and interview with the Technical Supervisor (TS)#1, the laboratory failed to document the intended staining characteristics for each day microscopic urinalysis slides were stained with KOVA Stain and manual differential slides were stained with Wright-Giemsa Stain Quicklink I. Findings include: 1. Review of laboratory records revealed the laboratory failed to document the staining quality of microscopic urinalysis slides or manual differential slides each day of testing. 2. Interview on May 13, 2021 at 9:30 AM with TS #1, confirmed the laboratory failed to document staining quality for either microscopic urinalysis slides stained with KOVA Stain or manual differential slides stained with Wright-Giemsa Stain Quicklink I.</p>
<b>D5553</b>	<p><b>IMMUNOHEMATOLOGY</b> CFR(s): 493.1271(b)(f)</p> <p>(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.</p>

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 document the visual inspection and record the temperature of blood and blood products upon receipt of new shipments and release of blood or blood products to be transfused for years 2019 and 2020. Findings: 1. Review of Blood Banking records lacked documentation of visual inspection and temperature checks upon receipt and release of blood and blood products for years 2019 and 2020. 2. Review of American Red Cross Hospital Partner Resource Guide revealed (page 17), "If products are received out of shipping temperature range or are packed incorrectly, notify Red Cross Customer Service. These products will be managed based on the non-conformance." 3. Interview with (TS)#1 on May 13, 2021 at 11:00 AM, confirmed the laboratory failed to document visual inspection and record the temperature of blood and blood products upon receipt of new shipment and release of blood and blood products to be transfused for years 2019 and 2020.

**D5555**

**IMMUNOHEMATOLOGY**  
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 review of the blood bank procedure, documentation of 2019, 2020 blood bank refrigerator and freezer alarm checks, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform and document regular alarm inspection checks for the blood bank refrigerator and freezer. Findings: 1. Review of the Blood Banking procedure (page 1) revealed, "We will check the alarm on the blood bank refrigerator and freezer three times per year." 2. Review of the 2019, 2020 documentation for alarm checks revealed the laboratory performed alarm checks on July 2, 2019; December 5, 2019; no documents were available for year 2020. 3. Interview with the TS #1 on May 13, 2021 at 11:15 AM confirmed the laboratory failed to regularly perform and document the alarm checks 3 times a year to monitor proper blood and blood product storage temperatures.