

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409901	(X3) Date Survey Completed 09/08/2022
Name of Provider or Supplier Rosebud Healthcare Center	Street Address, City, State 383 North 17th Avenue, Forsyth, 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, policy and procedure, 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 returned blood and blood products not used for transfusion from March 18, 2021, to September 8, 2022. Findings: 1. Review of Vitalant's packing slips lacked documentation of temperatures for blood and blood products upon receipt of new shipments and the Blood Bank Worksheet lacked documentation of temperatures for unused blood or blood products returned to the laboratory. 2. Review "Donor Unit Disposition" policy lacked instruction for recording temperatures upon receipt or new shipments of blood or blood products or units returned to the laboratory. 3. Interview with TS #1 on September 8, 2022, at 10:38 AM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and returned blood or blood products not used for transfusion.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or</p>

produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with Technical Supervisor (TS) #1, the laboratory failed to perform quality checks (QC) for sterility and ability to support growth for each new lot or shipment for three of three medias from January 1, 2020, to August 8, 2022. Findings: 1. On August 8, 2022, media was observed in the laboratory refrigerator, including Blood agar (BAP), Colistin and Nalidixic Acid (CNA) and MacConkey Agar (MAC). 2. Review of the microbiology worksheet lacked documentation of media QC to support growth and sterility for BAP, CNA, and MAC media. 3. Review of procedures lacked an IQCP for alternative QC practices. 4. Interview with TS #1 on September 8, 2022, at 3:29 PM, confirmed these findings.

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 review of policy and procedures, records, and interview with Technical Supervisor (TS) #1, the laboratory failed to consistently document the required information including visual inspection checks for 12 out of 29 units of blood or blood products released for transfusion or returned for reissue from January 01, 2021, to August 24, 2022. Findings: 1. Review of "Donor Unit Disposition" policy revealed "With the nurse, complete the 'issue' portion of the Unit Disposition section of the Blood Bank Worksheet" and "The 'return' portion of the Unit Disposition section of the Blood Bank Worksheet must be completed." 2. Review of "Blood Bank Worksheet" lacked one or more of the required information for either units "Issued (Date/Time, visual inspection, issued to, issued by) " or "Returned (Date/Time, OK for Reissue By)" on the following dates: 01/01/2021, 07/08/2021, 08/09/2021, 12/02/2021, 04/17/2022, and 4/25/2022. 3. Interview with TS #1 on September 8, 2022, at 11:00 AM, confirmed these findings.