Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0665042	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Roundup Memorial Healthcare	1202 3rd Street West, Roundup, 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 observation, record review, and interview with Technical Supervisor (TS) #2, the laboratory failed to ensure the appropriate temperature is maintained during the time blood and blood products are shipped for years 2019 and 2020. Findings: 1. Review of Immunohematology records lacked documentation of visual inspection and temperature of blood and blood products upon receipt of new shipments for years 2019 and 2020. 2. Observation of shipping containers revealed the lack of thermometers to monitor blood or blood components temperatures during shipment and upon receipt. 3. Review of Vitalant website revealed, "The receiving hospital must inspect the packing configuration and document acceptability, measure and record the receipt temperature of the shipment, verify shipper contents and sign the "Received By" section of the form, recording the date and time of receipt. Send a completed copy of the form to the local Vitalant center and retain a copy at the facility." 4. Interview with TS#2 on April 28, 2021 at 12:30 PM, confirmed the laboratory failed to ensure appropriate monitoring of blood and blood products during shipment and document acceptability, measure and record the receipt temperature of the shipment for years 2019 and 2020. .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of policy and procedure manual, laboratory records and interview with the Technical Supervisor (TS)#2, the laboratory failed to document the intended staining characteristics for each day manual differentials slides were stained. Findings include: 1. Review of hematology records revealed the laboratory failed to document the staining quality of manual differential slides each day of staining for years 2019 and 2020. 2. Review of policy # LAB 07.74, lacked how the laboratory would document staining quality control checks on manual differentials slides. 3. Interview on April 26, 2020 at 10:30 AM with TS #2, confirmed the laboratory failed to document staining quality of manual differential slides for years 2019 and 2020. .
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 records, policy and procedure manual, and interview with the Testing Personnel (TP)#3; (3 of 4), the laboratory failed to document visual inspection and record temperature upon receipt of new shipments of blood and blood products for 2019 and 2020 Findings: 1. No documentation of visual inspection and temperature of blood and blood products upon receipt of new shipments for years 2019 and 2020 were available for review. 2. Review of policy, Lab 11.30 Storage of Biologicals-Blood Products states "1. Inspect blood products/blood units prior to storage" 3. Review of policy, Shipping/Distribution (121A) states "Blood Component receipt temperature must be documented." 4. Interview with TP#3 on April 28, 2021 at 11:30 AM, stated the laboratory does not document visual inspection and temperature upon receipt of new shipments of blood and blood products upon arrival. .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS)#2, the laboratory failed to include the normal reference ranges in the patient results report for Microscopic Urine Analysis (UA): white blood cells (WBC), red blood cells (RBC),

	and epithelial cells. Findings: 1. Review of Microscopic Urine Analysis results for patient results report: Accession #19-245-1011 lacked a normal reference range for UA Micro Exam: WBS, RBC, and Epithelial Cells. 2. Interview on April 28, 2021 9: 17 AM with (TS)#2 confirmed the lack of normal reference ranges on the Microscopic Urine analysis patient results report. .