

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0411099	(X3) Date Survey Completed 06/28/2022
Name of Provider or Supplier St Luke Community Healthcare	Street Address, City, State 107 6th Avenue Sw, Ronan, 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, procedures, and interview with Technical Supervisor (TS) # 1, the laboratory failed to ensure the temperature was documented upon receipt of new shipments of blood products and of reissued blood products not used for transfusion from June 1, 2020 to June 28, 2022. Findings: 1. Immunohematology records lacked documentation of temperatures upon receipt of new shipments of blood products and of reissued blood products not used for transfusion from June 1, 2020 to June 28, 2022. 2. Review of laboratory procedures "Stock Inventory #8029" and "Return and Reissue of Blood for Transfusion #8033" lacked instructions for taking and recording temperatures for new shipments of blood products and unused blood products reissued. 3. The interview with TS #1 on June 28, 2022 at 2:30 PM, confirmed the laboratory failed to ensure the temperature was documented upon receipt of new shipments of blood products and reissued blood products not used for transfusion from June 1, 2020 to June 28, 2022.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on hematology and urinalysis record review, procedures and interview with the Technical Supervisor (TS) #1, the laboratory failed to include the normal reference ranges in the patient results reports for urinalysis(UA), manual cell count for body fluids (pleural and cerebral spinal) from June 1, 2020 to June 28, 2022. Findings: 1. Review of UA patient results report (#0628:U00002S), cell count for pleural fluid (#0628:HF00001S) and cell count for cerebral spinal fluid (#1120:HF00002R) lacked normal reference ranges. 2. Review of Hema 3 Stain and Routine Urinalysis procedures lacked information for normal reference ranges 3. Interview with TS #1 on June 28, 2022 at 11:30 AM , confirmed the patient results report lacked normal reference ranges for UA and cell counts for body fluids from June 1, 2020 to June 28, 2022.