

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410751	(X3) Date Survey Completed 11/29/2022
Name of Provider or Supplier Ruby Valley Hospital	Street Address, City, State 321 Madison St, Sheridan, 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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of maintenance documentation, policy and procedure manual, and interview with Technical Supervisor (TS) #1, the laboratory failed to establish and follow procedures for certifying one of one microscope and fume hood for accuracy. Findings: 1. Observed one microscope located in the laboratory. No certification stickers or records were available for review for years 2021 and 2022. 2. Review of Test Volume Report revealed three KOH preps, four Wet preps, and 15 microscopic uranalysis were performed using the microscope from November 29, 2021 to November 29 2022 (12 months). 3. Observed one fume hood in the laboratory with a function check sticker labeled "next service date 5/6/21". No other function check sticker or certification records were available for review from May 6, 2021, to November 29, 2022. 4. Review of "Quality Assurance" policy revealed the laboratory failed to define the type and frequency of the microscope and fume hood certification and failed to follow the policy to obtain "documentation of preventative maintenance, periodic inspections, and testing for proper operation of equipment and instruments." 5. Interview with TS #1 on November 29, 2022, at 1:30 PM, confirmed the laboratory failed to have the microscope and hood certified for accuracy.</p>

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, policy and procedures, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform monthly external quality controls (QC) as required by their Individualized Quality Control Plan (IQCP) for four out of twelve months in 2021. Findings: 1. Review of Quality Control procedure revealed the laboratory failed to follow their procedure as stated, "Liquid QC will be performed monthly, per IQCP" for the Alere Triage. 2. Review of Quality Control Worksheet for the Triage Ddimer revealed the laboratory failed to perform "External Quality Control: Positive and Negative QC each new lot and each new shipment, every 30 days", 3. A record review of external liquid QC checks for Ddimer lacked both a positive and negative QC check for June, July, September, and November of 2021. 5. Interview with the TS #1 on November 29, 2022, at 3:00 PM, confirmed the laboratory failed to perform external liquid QC monthly as required by their Triage Ddimer IQCP for June, July, September, and November of 2021.

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 document visual inspection checks for blood units released for transfusion from January 01, 2021, to July 26, 2022. Findings: 1. Review of "Release of Blood Product" procedure revealed the laboratory failed to document visual inspections performed, as stated "3. Both check out staff will inspect the blood unit for any leaks, clots, clumps, discoloration, or signs of contamination" 2. Review of "Blood Bank Record" lacked visual inspection documentation for blood units released for transfusion from January 1, 2021 to July 26, 2022. 3. Interview with TS #1 on November 29, 2022, at 11:00 AM, confirmed the lack of visual inspection documentation on the Blood Bank Records for blood units released from January 01, 2021, to July 26, 2022.