

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0410751	<b>(X3) Date Survey Completed</b>  08/29/2024
<b>Name of Provider or Supplier</b>  Ruby Valley Hospital	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5026</b>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1217</p> <p>If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on a record review of immunohematology and the laboratory's procedures, the laboratory failed to follow their procedure to ensure the blood bank reagents were not used past their expiration date (refer to D5417); failed to follow their procedure to perform and document quarterly maintenance for the Grifols DG Gel 8 Manual System (refer to 5431); failed to follow their procedure to perform blood bank quality control (QC) each day of patient testing (refer D5551); and failed to perform and document quarterly alarm checks (refer to D5555).</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical supervisor (TS) #1, the laboratory failed to establish a procedure and perform competency assessments for the technical supervisor and general supervisor listed on the CMS-209 Personnel Report form from August 29, 2022, to August 29, 2024, and failed to follow their procedure to assess three out of three new hires prior to patient testing and/or at six months after</p>

employment. Findings: 1. A review of the CMS-209 Personnel Report Form revealed one personnel listed as general supervisor and technical supervisor and lacked a competency assessment based on the position responsibilities from August 29, 2022, to August 29, 2024. 2. A review of the Competency Assessments procedure lacked the frequency of the technical supervisor and general supervisor competency assessment based on their federal regulatory responsibilities. 3. The laboratory failed to follow their Competency Assessments procedure to either assess initial hires (during training) and/or at 6-months after employment for three out of three laboratory testing personnel (TP) (TP# 1, 2, and 3). 4. An interview with TS #1 on August 29, 2024, at 8:30 AM confirmed the laboratory failed to follow their procedure to perform initial and/or 6-month assessments on new hires and lacked a procedure to perform and assess the technical supervisor and general supervisor based on the position responsibilities from August 29, 2022, to August 29, 2024.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on a record review, procedure, and an interview with the technical supervisor (TS) #1, the laboratory failed to follow their procedure to ensure the blood bank's Grifols DG Gel 8 test system reagents and DG Gel Essential Controls were not used past their expiration date for eleven patients tested from March 6, 2023, to June 28, 2023. Findings: 1. A review of the "DG Gel Essential Control Log" revealed staff failed to prevent the use of expired reagents (Grifols Diluent expired 3/31/2023, A1 Reverse-Cyte, B Reverse-Cyte, Seach-Cyte-Plus I, and Search-Cyte Plus II expired 3/18/2023), DG Essential quality controls (QC) (QC11 and QC12 expired 3/18/2023), and cards (DG Gel 8 A/B/D card expired 2/28/23, DG Gel 8 Neutral card expired 3/31/2023 and DG Gel 8 Anti-IgG expired 3/31/2023) to test three patients on 3/6/2023, 4/10/2023 and 5/4/2023. 2. A review of the "DG Gel Essential Control Log" revealed expired QC (QC11 and QC12 expired 5/13/2023) were used to perform testing on 5/22/2023, 6/14/2023, 6/21/2023, and 6/28/2023 for eight patients. 3. A review of the "Grifols DG Gel 8 Quality Control" procedure revealed that the laboratory failed to follow their procedure to not use reagents and controls beyond the expiration date. 4. An interview with TS #1 on August 29, 2024, at 3:30 PM confirmed the laboratory staff failed to follow their procedure to not use expired Grifols DG Gel 8 test system reagents and DG Gel Essential Controls on eleven patients tested from March 6, 2023, to June 28, 2023.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on record review, procedures, and an interview with the technical supervisor (TS) #1, the laboratory failed to follow their procedure to perform and document quarterly maintenance for the Grifols DG Gel 8 Manual System from January 1, 2023, to March 5, 2024. Findings: 1. A review of the "Blood Bank Temperature and Maintenance Log" lacked documentation of quarterly maintenance for the Card Probe Temperature, DG Therm Timer P1 and P2 Check, DG Therm Card Elevator Check, DG Spin RPM Check, DG Spin Timer Check, and DG Spin out of Balance Check as required by their "Grifols DG Gel 8 Manual System Maintenance" procedure to preserve the function of the Grifols DG Gel 8 Manual System. 2. An interview with TS #1 on August 29, 2024, at 1:30 PM confirmed the laboratory failed to follow their procedure to perform and document quarterly maintenance for the Grifols DG Gel 8 Manual System from January 1, 2023, to March 5, 2024.

**D5551**

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

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 a review of blood bank records, procedures and an interview with the technical supervisor (TS) #1, the laboratory failed to follow their procedure to perform blood bank quality control (QC) each day of patient testing for five out of five patients transfused from June 15, 2023, to August 23, 2023, and one API proficiency testing event performed on August 19, 2023. Findings: 1. A review of the "DG Gel Essential Control Log" revealed staff failed to follow their "Grifols DG Gel 8 Quality Control" procedure to perform QC each day a patient was tested and then transfused on 6/15/2023, 6/23/2023, 6/26/2023, 8/8/2023, and 8/23/2023. 2. A review of the API Proficiency testing records and "DG Gel Essential Control Log" revealed quality control was not performed on 8/19/2023, the day of testing. 3. An interview with TS #1 on August 29, 2024, at 3:15 PM confirmed the laboratory failed to perform QC each day patients were tested, and on the day proficiency testing was performed from June 15, 2023, to August 23, 2023.

**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 a review of procedures, blood bank records, and an interview with the technical supervisor (TS) #1, the laboratory failed to perform and document quarterly alarm checks to ensure storage conditions for four of four Red Blood Cells (RBCs) units are properly monitored from January 1, 2023, to March 5, 2024, for one Helmer Refrigerator. Findings: 1. A review of the "Blood Bank Temperature and Maintenance Log" lacked documentation of quarterly maintenance of their Helmer refrigerator's alarm system for the year 2023, as required by their "Helmer Refrigerator Maintenance" procedure to ensure the proper monitoring of the storage temperature of two group O Rh(D)-negative and two group O Rh(D)-positive Red Blood Cells (RBCs) units maintained in inventory. 2. An interview with TS #1 on August 29, 2024, at 1:30 PM confirmed the laboratory failed to perform and document quarterly alarm checks from January 1, 2023, to March 5, 2024.

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Based on record review, procedures, and an interview with technical supervisor (TS) #1, the laboratory failed to perform comparison studies twice a year and define the relationship between the test results using two different chemistry analyzers and manual and automated differential blood count from August 29, 2022, to August 29, 2024. Findings: 1. No comparison studies between the Siemens Dimension EXL 200 and Abbott i-STAT for the analytes: sodium, potassium, chloride, ionized calcium, total CO (2), glucose, blood urea nitrogen (BUN), and creatinine were available for review. 2. No comparison studies between manual differential blood count and automated differential blood count performed on the Sysmex XS 1000i were available for review. 3. No procedures for comparison studies to include a written criteria for acceptable differences in test values for chemistry and differential blood count were available for review. 4. An interview with TS #1 on August 29, 2024, at 10:30 AM confirmed the laboratory failed to perform comparison studies twice a year and define the relationship between the test results between two chemistry analyzers (Siemens Dimension EXL 200 and Abbott i-STAT) and manual and automated differential blood count from August 29, 2022, to August 29, 2024.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on immunohematology record review, policy and procedures, and an interview

with the technical supervisor (TS) #1, the laboratory director (LD) #1 failed to ensure that the quality assessment program was maintained and effectively monitored by laboratory staff from August 29, 2022, to August 29, 2024. Findings: 1. The laboratory director failed to follow the Grifols DG Gel 8 Quality Control procedure to review and sign the DG Gel Essential Control Logs and failed to follow the Grifols DG Gel 8 Manual System Maintenance procedure to review and sign the Blood Bank Temperature and Maintenance Log to ensure staff are performing duties as assigned. 2. The laboratory director failed to ensure the laboratory manager follow the "Blood Bank Documentation and Review" procedure to perform monthly reviews of blood bank records and provide those documents for quarterly review to the laboratory director. 3. The laboratory director failed to ensure staff do not use expired blood bank reagents and staff performed quarterly blood bank alarm check and DG Gel 8 maintenance (refer to D5417, D5431 and D5555). 4. An interview with TS #1 on August 29, 2024, at 4:39 PM confirmed the laboratory failed to ensure laboratory staff maintained the quality assurance program of the above-listed items from August 29, 2022, to August 29, 2024.