Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	27D0409901	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rosebud Healthcare Center	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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review, procedures and interview with the technical supervisor (TS) #1, the laboratory failed to follow their procedure to perform two levels of quality control (QC) every 24 hours with patient testing performed on the CLINITEK Status urinalysis analyzer for seven out of 17 days of patient testing in March 2023 and twelve out of 22 days of patient testing in December 2023 and failed to have a step-by-step procedure for how staff perform a historical record check of blood bank patient data to determine previously identified antibodies and any other serological anomalies and a procedure to detect and resolve ABO discrepancies from August 14, 2022, to August 14, 2024. Findings: 1. A review of American Proficiency Institute 2023 Hematology/Coagulation records revealed testing personnel failed to perform two levels of QC on 03/15/2023, the day of testing for Urinalysis Blood or Hgb Event 1. 2. A review of urinalysis QC logs revealed laboratory staff failed to perform two levels of quality control every 24 hours with patient testing per their "Clinitek Status Urinalysis" procedure for the following days of patient testing: 3/07/23, 3/08/23, 3/09/23, 3/15/23, 3/17/23, 3/22/23, 3/23/23, 12/05/23, 12/06/23, 12/07/23, 12/08/23, 12/11/23, 12/12/23, 12/21/23, 12/24/23, 12/25/23, 12/27/23, 12/28/23, and 12/19/23. 3. The laboratory failed to have a procedure for checking historical blood bank patient data to determine previously identified antibodies and any other serological anomalies and how to detect and resolve ABO discrepancies at the time of the survey. 4. An interview with TS #1 on August 14, 2024, at 1:00 PM and 2:45 PM confirmed staff failed to perform two levels of QC every 24 hours for the CLINITEK Status urinalysis

	analyzer for the days listed above and failed to have a step-by-step procedure for how staff perform a historical record check of blood bank patient data to determine previously identified antibodies and any other serological anomalies and a procedures to detect and resolve ABO discrepancies from August 14, 2022, to August 14, 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 ensure eight of ten microbiology American type culture collection (ATCC) quality control swabs and two of four biochemical reagents were not used on patient urine cultures past their expiration date from March 1, 2023, to August 14, 2024. Findings: 1. A review of Microbiologic's packing slip revealed the laboratory used expired ATCC quality control swabs to perform quality control checks on MicroScan gram negative (NUC85) and gram positive (PC45) panels, Columbia-Colistin Nalidixic Acid Agar (CNA), Blood Agar, and MacConkey Agar (MAC), and biochemical reagents staphlatex, catalase, coagulase, and oxidase from February 29, 2024, to August 14, 2024, with the following ATTC strains: a. Escherichia coli ATCC control #24922 with an expiration date of 3/31/24 b. Enterococcus faecalis ATCC control #29212 with an expiration date of 4/30/24 c. Klebsiella quasipneumoniae ATCC control #700603 with an expiration date of 4/30 /24 d. Enterococcus faecalis ATCC control #51299 with an expiration date of 2/29/24 e. Proteus vulgaris ATCC control #49132 with an expiration date of 3/31/24 f. Streptococcus gallolyticus ATCC control #49147 with an expiration date of 6/30/24 g. Micrococcus luteus ATCC control #49732 with an expiration date of 2/29/24 h. Klebsiella oxytoca ATCC control #49131 with an expiration date of 4/30/24 2. A review of QC results for microbiology biochemical reagents and patient urine culture worksheets revealed the laboratory used expired Oxidase reagent lot #501335 with an expiration date of 2/06/23 on seven out of seven patients tested in March 2023 and Catalase reagent lot #61551 with an expiration date of 4/24 on 11 of 11 patients tested in April 2024. 3. An interview with TS #1 on August 14, 2024, at 3:14 PM with TS #1 confirmed the laboratory failed to ensure ATCC QC swabs and biochemical reagents oxidase and catalase were not used on patient urine cultures past their expiration dates from March 1, 2023, to August 14, 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 the blood bank's procedures and an interview with the technical supervisor (TS) #1, the laboratory failed to have a procedure for the method of collecting and identifying the blood samples of recipients to ensure positive identification, procedures to expedite transfusion in life-threatening emergencies, records to be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician, and establish a policy for when testing for weak D must be performed from August 14, 2022, to August 14, 2024. Findings: 1. The laboratory failed to provide a procedure for the method of collecting and identifying the blood samples of recipients to ensure positive identification. 2. The laboratory failed to provide procedures to expedite transfusion in life-threatening emergencies, records to be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician. 3. The laboratory failed to establish a policy for when testing for weak D must be performed. 4. An interview with TS #1 on August 14, 2024, at 2:45 PM confirmed the laboratory failed to have the above-listed procedures for blood bank from August 14, 2022, to August 14, 2024.