Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520487	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Caribou Medical Center	300 South 3rd West, Soda Springs, ID	

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 review of the laboratory's procedure, direct observation, and interview with the laboratory manager on 12/4/2024, the laboratory failed to follow their policy and centrifuge urine at 400 g for urine sediment examinations. The findings include: 1. A review of the laboratory's policy, CMC - Laboratory Urinalysis & Microscopy Urine Analysis with Culture Criteria: "Centrifuge tubes for five (5) minutes at 400 g. (1500 rpm with a 15.25 cm radius head). " 2. A direct observation of the centrifuge on 12/4 /2024 at 10:51 am, the centrifuge displayed 600 RCF at 2200 RPM identified that the laboratory failed to follow their procedure. 3. In interview with the laboratory manager on 12/4/2024 at 10:51 am verified that the centrifuge setting was not following the facility's policy. 4. The laboratory performs 548 urine sediment examinations per year.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, patient test reports, and an interview with the laboratory manager on 12/4/2024, the laboratory failed to include the interpretation of results and define each range per field within the grading scale points of 1+, 2+, 3+, 4+ for urine sediment examinations in the procedure. The findings include: 1. A review of the laboratory procedure, titled CMC - Laboratory Urinalysis & Microscopy Urine Analysis with Culture Criteria, identified that the laboratory failed to define the range or interpretation of results for each grading scale point of 1+, 2+, 3+, 4+ for Red Blood Cells (RBC), White Blood Cells (WBC), crystals, yeast, bacteria, epithelial cells, mucus, parasites, and other formed elements. 2. A review of the patient test report for MRN 7430 tested on 11/2/2024 had the following UA microscopic sediment interpretation : UA WBC 2+ UA RBC none seen UA Bacteria 2+ UA Amorph 2+ 3. An interview with the laboratory manager on 12/4/2024 at 9:36 am confirmed that the grading scale of 1+, 2+, 3+, 4+ for microscopic urine sediment examination was not defined in the procedure. 4. The laboratory reports performing 548 urine sediment examinations annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, and an interview with the laboratory manager on 11/4 /2024, the laboratory failed to label a secondary container containing stain with it's identification and expiration date. The findings include: 1. A direct observation on 11 /4/2024 at 10:49 am in the laboratory, identified a secondary container containing stain that the laboratory failed to label with the stain name and expiration date. 2. An interview with the laboratory manager on 12/4/2024 at 10:49 am confirmed that the container needed to be labeled with Wright stain and an expiration date. 3. The laboratory reports performing 5,289 automated and manual differentials annually.
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 a review of a laboratory patient report and an interview with the laboratory manager on 12/4/2024, the laboratory failed to include the reference or normal ranges for analytes in urinalysis examinations on final patient reports. The findings include: 1. A review of the laboratory patient report for MRN 7430 from 11/17/2024 identified that the laboratory failed to include the reference or normal ranges for leukocyte esterase, nitrate, protein, ketones, urobilinogen, bilirubin, blood, pH, specific gravity, white blood cells, red blood cells, casts, mucous, yeast, crystals, bacteria, parasites and epithelial cells for urine macroscopic and microscopic testing. 2. An interview with the laboratory manager on 12/4/2024 at 10:20 am confirmed the laboratory failed to have reference ranges on final reports for urinalysis examinations. 3. The laboratory reports performing 548 urinalysis examinations annually.