Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520487	(X3) Date Survey Completed 12/10/2018
Name of Provider or Supplier Caribou Medical Center	**Street Address, City, State** 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory failed to enroll in a PT program that covers the type of testing performed in the specialty of bacteriology since the last survey on July 25, 2017. Findings: 1. A record review of the American Association of Bioanalysts PT documents revealed the laboratory failed to enroll in PT for the interpretation of gram stains. 2. An interview on December 10, 2018 at 9:35 A.M. with the laboratory manager, confirmed the microbiology laboratory failed to enroll for testing in gram stain interpretation.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed

	by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory director or designee and the testing personnel failed to sign the attestation statements from the American Association of Bioanalysts (AAB) and the American Proficiency Institute (API). This is a repeat deficiency from the last survey on July 25, 2017. Findings: 1. A review of AAB and API PT records revealed the laboratory director or designee and the testing personnel failed to sign the attestation statements for the specialties of bacteriology, chemistry, hematology, immunohematology, endocrinology, toxicology, and virology for the three testing events reviewed in 2018 and event 3 in 2017. 2. An interview on December 10, 2018 at 9:35 A.M. with the laboratory manager, confirmed the laboratory failed to sign the attestation forms from AAB and API during the third event reviewed in 2017 and events 1, 2, and 3 in 2018.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on records review and an interview with the laboratory manager, the laboratory failed to retain quality control and patient test print-outs from the iSed instrument since the last survey on July 25, 2017. Findings: 1. A review of records for the iSed sedimentation rate instrument revealed the laboratory failed to retain quality control and patient test print-outs. 2. An interview on December 10, 2018 at 1:25 P.M. with the laboratory manager, confirmed the testing personnel failed to retain the quality control and patient test print-outs for the instrument.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if

	applicable. This STANDARD is not met as evidenced by: Based on a review of patient test requisitions and an interview with the laboratory testing person, the laboratory failed to solicit the patients ' date of birth or sex and age from the 3 requisitions reviewed in February 2018. Findings: 1. A review of 3 patient test requisitions from February 2018, revealed the laboratory failed to document the patients ' date of birth or sex and age on the requisitions. 2. An interview on December 10, 2018 at 2:35 P.M. with the laboratory testing person, confirmed the laboratory failed to solicit and document the patient ' s date of birth.
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 an observation, a record review, and an interview with the laboratory manager, the laboratory failed to document the expiration dates for the SediTrol sedimentation rate liquid quality controls since the last survey on July 25, 2017. Findings: 1. An observation at 1:15 P.M. of the laboratory, revealed an Alcor iSed instrument with two levels of SediTrol quality control vials in the rack without open or expiration dates on the vials. 2. A record review revealed the laboratory failed to maintain lot numbers, dates in use, and expiration dates of the quality control vials. 3. An interview on December 10, 2018 at 1:20 P.M. with the laboratory manager, confirmed the laboratory tested the quality control material until the vials were empty and did not know about the expiration dates for the material.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review of quality control results and an interview with the laboratory manager, the laboratory failed to ensure two levels of external quality control results for Prothrombin Time (PT) met the manufacturer's requirement for acceptability before reporting patient PT results for the time reviewed between September 2, 2018 and October 31, 2018. Findings: 1. A review of the Stago PT quality control results from September 2, 2018 through October 31, 2018 revealed 6 days when level 2 control was out of range and 1 day when level 1 was out of range. 2. An interview on December 10, 2018 at 2:00 P.M. with the laboratory manager, confirmed the laboratory failed to meet the manufacturer's quality control acceptability prior to reporting 7 patient PT results.

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 record review and an interview with the laboratory manager, the laboratory failed to write a policy or procedure and failed to perform immediate spin compatibility testing to detect IgM antibodies since the last survey on July 25, 2017. Findings: 1. A review of blood bank documents revealed the laboratory failed write a procedure and failed to perform an immediate spin crossmatch for the detection of IgM antibodies for ABO incompatibilities. 2. An interview on December 10, 2018 at 11:55 A.M., with the laboratory manager, confirmed 2 out 3 testing personnel failed to perform an immediate spin to demonstrate ABO incompatibilities on patient specimens.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on patient record reviews, proficiency testing (PT) record reviews, and an interview with the laboratory manager, the laboratory failed to maintain test records to include the dates of bacteriology test performances and the testing personnel who performed bacteriology workups such as culture set-up on media, colony description and quantitation, and gram stains since the last survey on July 25, 2017. Findings: 1. A review of the American Proficiency Institute bacteriology PT worksheets revealed the laboratory failed to document culture procedures that include: a. the type of media used, b. the colony description, quantitation, and morphology, c. the individual performing each step of testing from streaking of the plate to final reporting, d. and the lot numbers and dates of each test performance. 2. A review of patient test records revealed the laboratory failed to identify the dates, testing personnel, and bacteriology tests performed on culture workups. 3. An interview on December 10, 2018 at 3:05 P. M., with the laboratory manager, confirmed the laboratory failed to document all bacteriology tests performed.