Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520463	12/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bear Lake Memorial Hospital	164 S 5th St, Montpelier, 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 from the American Association of Bioanalysts (AAB) 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 26, 2017. Findings: 1. A record review of the AAB PT documents revealed the laboratory failed to enroll in PT for the interpretation of gram stains. 2. An interview on December 13, 2018 at 9:15 A.M. with the laboratory manager, confirmed the microbiology laboratory failed to enroll for testing in gram stain interpretation.
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 reviewed and an interview with the laboratory manager, the laboratory failed to retain instrument quality control and patient print-outs, as well as quality control assay sheets from the Osmometer, the Excyte Mini sedimentation, and ABL 80 blood gas instruments since the last survey on July 26, 2017. Findings: 1. A review of records for the Excyte Mini sedimentation rate instrument revealed the laboratory failed to retain quality control and patient test print-outs. 2. An interview on December 13, 2018 at 1:25 P.M., with the laboratory manager, confirmed the testing personnel failed to retain instrument printouts for quality controls and patient tests for the instruments.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to verify the accuracy of total thyroxine scored an artificial 100% for events 1 and 2 in 2018. Findings: 1. A review of AAB PT documents revealed the laboratory failed to evaluate all artificial scores received from AAB for total thyroxine for events 1 and 2 in 2018. 2. An interview on December 13, 2018 at 9:15 A.M., with the laboratory manager, confirmed artificial scores of 100% received from AAB for the analyte were not evaluated and verified for accuracy.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to verify the accuracy of microscopic urine sediment examinations, manual cell counts, and direct, conjugated and unconjugated bilirubin at least twice during 2018. This is a repeat deficiency from the last survey on July 26, 2017. Findings: 1. A review of AAB PT documents revealed the laboratory failed to verify the accuracy of microscopic urine sediment examinations, manual cell counts, and direct, conjugated and unconjugated bilirubin at least twice a year in 2018. 2. An interview on December 13, 2018 at 9:15 A.M., with the laboratory manager, confirmed the analytes were not verified for accuracy at least twice a year.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to document the evaluation and corrective actions for unsatisfactory, unacceptable, and ungraded PT results during 2018. Findings: 1. A document review of PT results from AAB revealed the laboratory failed to document the evaluation and corrective actions taken for unsatisfactory direct bilirubin in events 2 and 3 and blood gas pH in event 3, as well as unacceptable results for pCO2 in event 3 and cell identification in event 2 2018. 2. A document review of PT results from AAB revealed the laboratory failed to document the evaluation and corrective actions taken for ungraded results for total thyroxine in event 1 and 2 2018 and blood gases in event 3 2018. 3. An interview on December 13, 2018 at 9:55 A.M., with the laboratory manager, confirmed the laboratory failed to document the evaluation and corrective actions of unsatisfactory, ungraded, or unacceptable PT results in 2018.
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 a review of instrument records and an interview with the laboratory manager, the laboratory failed to ensure proper identification of patient results and failed to indicate the dates of testing and testing personnel performing the tests since the last survey on July 26, 2017. Findings: 1. A review of the instrument printouts from the Excyte Mini sedimentation rate and the Osmometer revealed the testing personnel failed to indicate the date test was performed, the patient identifiers, and the testing personnel. 2. An interview on December 13, 2018 at 2:35 P.M., with the laboratory manager, confirmed the patient identifiers, testing personnel and the dates performed were not stated on the instrument printouts.