Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0056312	08/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Big Horn Hospital District	1115 Lane 12, Lovell, WY	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the laboratory director failed to sign and date as approved 1 new test system procedure for the XN 550 complete blood cell counter prior to use and failed to sign and date as approved 2 of 6 test systems in use prior to the change of director (Cobas e411 and c311 chemistry analyzers). The laboratory tested approximately 1500 complete blood count specimens per year and 70,000 specimens per year for tests performed on the chemistry analyzers. Findings include: 1. The operator's manual for the XN 550 instrument failed to include the director's signature and date of approval prior to using the instrument to test and report patient specimens. 2. The operator's manual for the Cobas e411 and c311 failed to include the date of approval by the current director. 3. In an interview on 08/03/2018 at approximately 4:00 P.M., the laboratory manager stated the director signed the verification study and was not aware the operator's manual, serving as the procedure manual, also needed the director's signature and date of approval. The laboratory manager stated the operators manuals were the procedure manuals.
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 bacteriology organism identification reports review, lack of documentation and interview with staff, the laboratory failed to document the lot numbers and expiration dates of biochemical reagents to ensure the reagents were not used past their expiration dates for 1 of 6 biochemicals reviewed. The laboratory performed approximately 300 bacterial organism identifications annually. Findings include: 1. Microscan organism ID reports failed to include the accurate reagent lot number or expiration date. The Sulfanilic Acid culture organism test report stated the lot number was 2017/12/05. No expiration date was recorded. 2. Reagent containers lacked the manufacturer's expiration dates since the original expiration dates had been partially to completely rubbed off the label over time with use. 3. In an interview with the laboratory manager on 08/03/2018 at approximately 3:30 P.M., the laboratory manager confirmed the laboratory did not have a reliable source to determine the expiration date for the reagents used for identification of the cultured organism.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on new test verification studies review, lack of documentation and interview with staff, the laboratory failed to notify clients when the white blood cell differential test method changed the lymphocyte and monocyte white blood cell percentages. Findings include: 1. Verification studies included documentation the monocyte bias was 28.8% with an r value of 0.3497 and the lymphocyte bias was 17.4% with an r value of .896. (An R value of 1.0 is complete agreement.) 2. The laboratory failed to document clients were notified of the bias. 3. In an interview conducted on 08/03 /2018 at approximately 4:00 P.M., the laboratory manager stated staff were advised of the bias in the medical staff meeting but did not have written documentation of the notice.