Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0056312	09/01/2020
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 director failed to sign and date as approved a procedure for least incompatible blood compatibility testing prior to use since 09/01/2018. Findings include: 1. Procedure manual review included emailed instructions for testing personnel to follow for crossmatching a patient with multiple antibodies. The procedure was used following the reference laboratory identification of multiple Red Blood Cell antibodies. 2. The special procedure for least incompatible crossmatch failed to include the director's signature and date of approval. 3. In an interview conducted on 09/01/2020 at approximately 5:00 P.M., and via email on 09/03/2020, the laboratory manager confirmed the director had not approved the procedure for least incompatible blood transfusions. Staff stated the same patient returned on a regular basis for transfusion and the laboratory used the least incompatible procedure for compatibility testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on immunohematology records review, direct observation, Thermo Fisher Centra W cell washer/centrifuge operators manual review, lack of documentation, and interview with staff, the laboratory failed to document immunohematology centrifuge and cell washer revolutions per minute (RPM) and timer checks every three months for 2 of 2 years reviewed (September 2018 to the sticker dates of 2019 and 2020). The laboratory performed approximately 550 compatibility tests per year. Findings include: 1. Thermo Fisher operator's manual on page 4.2 specified RPM and speed functions be checked once every 3 months for the Centra W cell washer/centrifuge. 2. Immunohematology cell washer/centrifuge function check records review failed to include documentation of the 4th quarter 2018, 3 of 4 quarters of 2019 and 2 of 3 quarters of 2020 of RPM and timer checks for the Thermo Fisher Centra W cell washer/centrifuge used for A, B, O Group, Rh Typing, Antibody Screens, and Compatibility testing. Stickers were observed on 09/01/2020 at approximately 2:30 P. M. for one RPM and timer check in 2019 and one for 2020 and none in 2018. The dates the checks were performed were not noted by the surveyor. 3. In an interview with staff on 09/01/2020 at approximately 5:00 P.M., and also by email received on 09 /03/2020, the laboratory manager confirmed the laboratory lacked documentation of centrifuge speed (RPM) and timer checks to ensure optimal cell packing for immunohematology Grouping, typing, antibody screening, and compatibility interpretation.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on bacteriology test records review, lack of documentation, and interview with staff, the laboratory failed to check antibiotic susceptibility each day of testing for 2 of 2 days of testing reviewed 11/29/2018 and 08/26/2020. The laboratory performed approximately 362 susceptibility tests per year. Findings include: 1. Bacteriology test records review failed to include susceptibility quality control performed each day of testing for urine cultures collected on 11/28/2018 for an E. coli organism that was resistant to Ampicillin and Intermediate susceptibility against Ampicillin/Sulbactam; and on 08/27/2020 for K. ascorbata. 2. In an interview with staff on 09/01/2020 at approximately 5:00 P.M., staff stated the laboratory was operating under an Individualized Quality Control Plan (IQCP) for reduced frequency of susceptibility testing but was not able to locate the approved IQCP.