Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0056312	08/15/2024
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
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 review of proficiency testing records and staff interview, the laboratory failed to maintain a copy of each step in the testing and reporting of the WSLH (Wisconsin State Laboratory of Hygiene) proficiency samples for 7 of 47 proficiency testing events reviewed from September 2022 through July 2024. The findings were: 1. Review of the proficiency testing records showed no evidence of the following documentation: a. 2023 WSLH Blood Gas Event #2, Blood Gas Event #3, Special Chemistry Event #2, and Semen Analysis Event #2 was missing the performance summary and comparative evaluation indicating the results had been reviewed by the technical supervisor. b. 2023 WSLH Coagulation/Hematology Event #3 was missing the performance summary and comparative evaluation indicating the results had been reviewed by the technical supervisor. In addition, the data submission form, the attestation form, and the worksheets/instrument printouts could not be located. c. 2022 WSLH Semen Analysis Event #2 failed to include the sample worksheets. d. 2022 WSLH Miscellaneous Event #2 was missing the performance summary and comparative evaluation indicating the results had been reviewed by the technical

	supervisor. 2. Interview with the technical supervisor on 8/14/24 at 11:55 AM confirmed the proficiency testing documentation was incomplete.
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 review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to have a system in place for reviewing proficiency test results that received an artificial score of 100% for 3 of 47 WSLH (Wisconsin State Laboratory Hygiene) proficiency testing events reviewed from September 2022 to July 2024. The findings were: 1. Review of the WSLH 2023 Microbiology Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on the antibiotic susceptibility challenge. Minocycline and tetracycline were not scored due to an insufficient peer group; amoxicillin/clavulanate was not scored and the laboratory was directed to consult the event notes; and ceftriaxone was not scored due to non-consensus and a self-assessment was required. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 2. Review of the WSLH 2023 Chemistry/Endocrinology/Toxicology Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on the analyte of alanine aminotransferase and measured total iron binding capacity due to non-consensus and a self-assessment was required. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 3. Review of the WSLH 2022 Miscellaneous proficiency testing evaluation showed the laboratory received an artificial score of 100% on the manual identification of urine sediment. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 4. Interview with the technical supervisor on 8/14/24 at 11:55 AM confirmed no further documentation was available.
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 review of instrument maintenance records, lack of documentation, staff interview, and review of the Cepheid GeneXpertXpress operator's manual, the laboratory failed to follow the manufacturer's instructions to clean the cartridge bays and plunger rods on a quarterly basis for 5 of 6 quarters reviewed from January 2023 to June 2024. The findings were: 1. Review of the Cepheid GeneXpertXpress maintenance records showed no evidence the required quarterly maintenance on the

	analyzer had been completed as required. 2. Review of the Cepheid GeneXpertXpress operator's manual showed the plunger rods and cartridge bays should be cleaned and disinfected quarterly (every 3 months). 3. Interview with technical supervisor on 8/15 /24 at 9:08 AM confirmed no further documentation was available.