Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 35D0409336	**(X3) Date Survey Completed** 09/23/2021
Name of Provider or Supplier Mckenzie County Healthcare Systems	**Street Address, City, State** 709 4th Ave Ne, Watford City, ND	
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**
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 record review, staff interview, and policy review, the laboratory failed to twice annually verify the accuracy of two of two non-regulated analytes (Human Immunodeficiency Virus antibody and Hepatitis C antibody) in 2020. The laboratory performed approximately 171 Human Immunodeficiency Virus (HIV) and 119 Hepatitis C antibody patient tests in 2020. Findings include: 1. Reviewed at 4:05 p.m. on 09/22/21, the laboratory's test menu listed HIV and Hepatitis C antibodies available for patient testing. 2. Reviewed at 4:10 p.m. on 09/22/21, the 2020 proficiency testing records indicated the laboratory did not participate in proficiency testing for HIV and Hepatitis C antibodies. 3. Upon request at 11:30 a.m. on 09/23/21, the laboratory failed to provide evidence of twice annual accuracy verification for HIV and Hepatitis C antibodies in 2020. 4. During interview at 12:45 p.m. on 09/23 /21, a general supervisor (Personnel #1) confirmed the laboratory performed HIV and Hepatitis C antibody patient testing in 2020 and did not twice annually verify the accuracy of these tests in 2020. 5. Reviewed at 2:40 p.m. on 09/23/21, the policy "Proficiency Testing Results," effective 06/14/18, stated, "Policy/Procedure . . . C. All non-regulated analytes are verified and documented 2X [times]/year."
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the technical supervisor failed to evaluate and document the competency at least semi-annually for two of four new testing personnel (Testing Personnel #1 and #2) hired in 2019-2020. Findings include: 1. Reviewed at 8:30 a.m. on 09/23/21, the competency evaluation records lacked evidence of six month competency evaluations for Testing Personnel #1 in 2020 and Testing Personnel #2 in 2021. 2. During interview at 12:20 p.m. on 09/23 /21, a general supervisor (Personnel #1) confirmed the technical supervisor had not completed six month competency evaluations for Testing Personnel #1 who started in November 2019 and for Testing Personnel #2 who started in July 2020. 3. Reviewed at 2:40 p.m. on 09/23/21, the policy "Competency," effective 06/18/18, stated, "Procedure . . . E. . . . competency testing is done in the Lab at 6 months . . ."
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the technical supervisor failed to evaluate and document the competency for one of three testing personnel (Testing Personnel #3) requiring annual competency evaluations in 2020. Findings include: 1. Reviewed at 8:30 a.m. on 09/23/21, the competency evaluation records lacked evidence of an annual competency evaluation for Testing Personnel #3 in 2020. 2. During interview at 12:20 p.m. on 09/23/21, a general supervisor (Personnel #1) confirmed the technical supervisor had not completed an annual competency evaluation in 2020 for Testing Personnel #3 who started in September 2019. 3. Reviewed at 2:40 p.m. on 09/23/21, the policy "Competency," effective 06/18/18, stated, "Procedure . . . E. . . . competency testing is done in the Lab at 6 months, then again annually. . . ."