Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409336	02/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mckenzie County Healthcare Systems	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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 1 of 3 chemistry events (Event 1) in 2024. Findings include: 1. Reviewed on 02/11/25, the Event 1-2024 chemistry proficiency testing records lacked evidence of results review and evaluation of analytes with less than 100% scores including: - D-dimer 60% - pH (potential of hydrogen) 80% - pCO2 (partial pressure of carbon dioxide) 80% - pO2 (partial pressure of oxygen) 80% 2. Reviewed on 02/11/25, the policy "Proficiency Program," dated 11/15/16, stated, ". . . Procedure . . . Evaluate all test results upon receipt. Graded specimens are reviewed. Document any corrective action. . . ." 3. During interview at 3:00 p.m. on 02/11/25, the laboratory manager (#1) confirmed the laboratory had failed to document review of the Event 1-2024 chemistry results and evaluation of the results with less than 100% scores.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A

	complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify calibration at least every six months for 1 of 2 endocrinology analytes (progesterone) calibrated with less than three calibrators on the Abbott Architect Plus in 2024. The laboratory performed approximately 50 progesterone patient tests in 2024. Findings include: 1. Reviewed on 02/11/25, the 2024 progesterone calibration records indicated the use of two levels of calibrators for calibration of progesterone. 2. Reviewed on 02/11/25, the 2024 calibration verification records failed to include verification of progesterone in the first six months. 3. Upon request on 02/11/25, the laboratory failed to provide evidence of calibration verification for progesterone in the first six months of 2024. 4. Upon request on 02/11/25, the laboratory failed to provide a policy regarding the requirement for at least twice annual calibration verification for analytes calibrated with less than three levels of calibrators. 5. During interview at 2:55 p.m. on 02/11/25, a technical supervisor (#2) confirmed the laboratory had failed to verify calibration at least twice annually for progesterone in 2024.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review, policy/procedure review, and staff interview, the laboratory failed to perform a positive and negative control each day of patient testing for bacterial vaginosis, vulvovaginal candidiasis, and trichomonias tests on the Cepheid GeneXpert for 4 of 4 patient testing days (12/03, 12/04, 12/13, and 12/23) in December 2024. The laboratory performed sixteen bacterial vaginosis, vulvovaginal candidiasis, and trichomonias patient tests on days with no quality control (QC) performance in December 2024. Findings include: 1. Reviewed on 02/11/25, the patient testing records for the Cepheid GeneXpert Multiplex Vaginal Panel (MVP) including undifferentiated organisms associated with bacterial vaginosis, undifferentiated Candida albicans/tropicalis/ parapsilosis/dubliniensis, undifferentiated Candida glabrata/krusei, and Trichomonas vaginalis indicated performance of patient testing on the following days in December 2024: 12/03, 12/04, 12/13, and 12/23. 2. Reviewed on 02/11/25, the December 2024 QC records for the MVP tests failed to include evidence of the performance of positive and negative controls on the following patient testing days: 12/03, 12/04, 12/13, and 12/23. 3. Reviewed on 02/11/25, the policy/procedure "Cepheid Genexpert MVP," dated 01/08 /2023, stated, ". . . Quality Control: . . . 3. External positive controls and the external negative control are tested with each new lot, each new shipment and monthly. . . ." The policy/procedure failed to require the performance of a positive and negative

	external control each day of patient testing. 4. During interview at 3:20 p.m. on 02/11 /25, a technical supervisor (#3) confirmed the laboratory failed to perform QC each day of patient testing for the MVP tests.