Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D2298302	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mckenzie Health Laboratory - Williston	3 4th St Suite 2, Williston, 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
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) 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. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to document proficiency testing results on the Quickvue Urine/Serum HCG (Human Chorionic Gonadotropin) test log for 3 of 3 Chemistry Core events (1st Event 2025, 2nd Event 2025, and 3rd Event 2025) reviewed. Findings include: 1. Review of API (American Proficiency Institute) proficiency testing records at 3:22 p.m. on 03/10/26, showed the 1st Event 2025, 2nd Event 2025, and 3rd Event 2025 Chemistry Core proficiency testing records lacked evidence of proficiency testing results on the Quickvue Urine/Serum HCG test log. 2. During interview at 3:30 p.m. on 03/10/26, the Laboratory Director (#1) confirmed testing personnel do not document HCG proficiency testing results on the Quickvue Urine/Serum HCG test log. 3. Reviewed the afternoon of 03/10/26, the policy "Proficiency Testing," dated 02/28/25, stated, "All proficiency test samples . . . are handled, processed, and tested in the same manner as patient samples."
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 review, and staff interview, the laboratory failed to perform a positive and negative control each day of serum HCG (Human Chorionic Gonadotropin) proficiency and patient testing for 5 of 11 days (08/27/25, 09/19/25, 09 /27/25, 12/16/25, and 12/30/25) reviewed. The laboratory performed 30 serum HCG patient tests the past year. Findings include: 1. Reviewed at 3:22 p.m. on 03/10/26, the 2025 Chemistry Core 3rd event proficiency testing records indicated performance of serum HCG testing on 08/27/25 using the test kit Quidel Quickvue hCG Combo Test. 2. Reviewed at 4:48 p.m. on 03/10/26, the 2025 serum HCG patient testing records indicated performance of patient testing on 09/19/25, 09/27/25, 12/16/25, and 12/30 /25. 3. Reviewed on 03/10/26, the policy "QuickVue hCG Combo TEST," dated 05/04 /24, stated, "QUALITY CONTROL . . . External Controls . . . are run each day of patient testing . . ." 4. Reviewed the afternoon of 03/12/26, the Serum HCG QC (quality control) Log failed to include evidence of the performance of positive and negative controls on 08/27/25, 09/19/25, 09/27/25, 12/16/25, and 12/30/25. 5. During an interview at 10:29 a.m. on 03/12/26, the Laboratory Director (#1) confirmed the Serum HCG QC Log does not include QC for 08/27/25, 09/19/25, 09/27/25, 12/16/25, and 12/30/25.