Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408612	07/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
First Care Health Center	115 Vivian St, Park River, 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
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 record review, staff interview, and policy review, the laboratory failed to verify the accuracy of results for 1 of 3 Chemistry Core events (Chemistry Core 2nd Event 2025) the American Proficiency Institute (API) assigned as not graded. The laboratory performed 4,370 total bilirubin patient tests in the past year. Findings include: 1. Reviewed the afternoon of 07/29/26, the 2nd Event 2025 Chemistry Core proficiency testing showed Total Bilirubin samples CH-07, CH-09, and CH-10 as not graded. The laboratory failed to evaluate the not graded results. 2. During an interview at 3:45 p.m. on 07/29/26, a Laboratory Manager (#1) confirmed the laboratory failed to evaluate the 2nd Event 2025 Total Bilirubin not graded results. 3. Reviewed on 07/29/26, the policy "Evaluation of Proficiency Testing Results," dated 07/2005, stated, ". . . Any analyte not evaluated . . . will be investigated. . . ."
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

	This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the Laboratory Director failed to ensure 5 of 5 testing personnel (Testing Personnel #1, #2, #3, #4, and #5) received appropriate training and demonstrated reliable testing performance before reporting patient results on two new moderately complex test kits (TechLab Leuko EZ Vue [detects fecal lactoferrin, a marker for fecal leukocytes] and Fisher Healthcare Sure-Vue STAT Serum/Urine HCG [human chorionic gonadotropin]). Findings include: 1. Reviewed at 11:12 a.m. on 07/29/26, the testing personnel records failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel (#1, #2, #3, #4, and #5) before reporting patient results on the TechLab Leuko EZ Vue and Fisher Healthcare Sure-Vue STAT Serum /Urine HCG test kits. 2. Reviewed at 5:32 p.m. on 07/29/26, the February 2025 verification of performance specifications records for the TechLab Leuko EZ Vue test kit failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel (#1, #2, #3, #4, and #5). 3. Reviewed at 5:40 p.m. on 07/29/26, the January 2025 verification of performance specifications records for the Fisher Healthcare Sure-Vue STAT Serum/Urine HCG test kit failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel (#1, #2, #3, #4, and #5). 4. Upon request on 07/29/26, the laboratory failed to provide evidence of training for Testing Personnel (#1, #2, #3, #4, and #5) for the TechLab Leuko EZ Vue and Fisher Healthcare Sure-Vue STAT Serum/Urine HCG test kits. 5. During an interview in the afternoon of 07/29/26, the Laboratory Manager (#1) stated Testing Personnel (#1, #2, #3, #4, and #5) had performed patient testing on the TechLab Leuko EZ Vue and Fisher Healthcare Sure-Vue STAT Serum/Urine HCG test kits and confirmed the laboratory failed to document training and demonstration of reliable testing performance for Testing Personnel (#1, #2, #3, #4, and #5) on the TechLab Leuko EZ Vue and Fisher Healthcare Sure-Vue STAT Serum/Urine HCG test kits. 6. Reviewed on 07/29/26, the policy "Method Evaluation," dated 07/2005, stated, ". . . Implementation . . . Instruct laboratory personnel on procedure . . ."