Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393107	06/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Prairie Clinic	112 Helen St, Sauk City, WI	

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
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and test procedures, and interview with testing personnel, the laboratory director did not ensure the laboratory sufficiently reviewed an unacceptable potassium result on the second chemistry event in 2021. The review did not show the laboratory took actions to ensure testing personnel repeated critical values before reporting the test result and ensure samples did not contain bubbles. The review also did not show the laboratory evaluated quality control or other indicators to ensure acceptable precision of the test system. Findings include: 1. Review of the Wisconsin State Laboratory of Hygiene PT report for the second Chemistry event (Chem/Endo/Tx2) in 2021 showed the laboratory reported a potassium result of 2.3 mmol/L (millimole per Liter) for sample CET-6. The expected result was 3.3 mmol/L with an acceptable range of 2.8 - 3.8 mmol/L. The laboratory documented the following on the PT report: "No flags on test - rerun - Better within range. No other flags on potassium, 80% passing, Bubble?" There was no evidence showing review of quality control or other records to evaluate the precision of the test system. There was no record showing review with testing personnel to ensure testing personnel remove bubbles from samples prior to testing. The PT records showed no evidence testing personnel repeated sample CET-6 prior to reporting the result. 2. Review of laboratory procedures showed potassium values below 3.0 mmol/L are

	critical and require repeat testing to verify the result. 3. Interview with testing personnel (staff A) on June 10, 2021 at 10:30 AM confirmed the review of the proficiency testing report did not reveal that testing personnel did not repeat the critical potassium value. Further interview confirmed the documentation did not show evaluation of potassium precision to determine whether corrective action was required and did not show the technical consultant reviewed the PT results with testing personnel to address repeating critical results or ensuring samples do not contain bubbles. This is a repeat deficiency previously cited on May 24, 2011.