

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0393107	<b>(X3) Date Survey Completed</b>  04/17/2023
<b>Name of Provider or Supplier</b>  Prairie Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs and corrective action records and interview with the laboratory supervisor, staff A, the laboratory did not document corrective action when equipment is not performing as expected for the Siemens Xpand chemistry analyzer for eight of eleven days in February 2023. Findings include: 1. Review of maintenance logs for the Siemens Xpand chemistry analyzer showed the daily system check failed on the following days: February 14: System check run twice. Second run passed. February 16: System check run twice. Second run passed. February 17: System check run twice. Second run passed. February 22: System check run twice. Both runs failed. February 23: System check run once. Run failed. February 24: System check run twice. Both runs failed. February 25: System check run three times. Third run passed. February 27: System check run twice. Second run passed. Further review showed no documentation the system check passed prior to use for three of eleven days. 2. Review of corrective action logs showed no documentation of corrective action for the subsequent runs on the Siemens Xpand</p>

chemistry analyzer in February 2023 3. Interview with the staff A on April 17, 2023, at 12:55 PM confirmed the laboratory did not document corrective action on the Siemens Xpand chemistry analyzer in February 2023.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, job descriptions and the CLIA Laboratory Personnel Report (CMS209) and interview with the laboratory supervisor, staff A, the laboratory director has not delegated responsibilities to a qualified individual per the organization's requirements for one of one personnel. Findings include: 1. Review of the "Delegation of Duties" procedure for the laboratory supervisor stated the following: "The Laboratory Supervisor is delegated the following responsibilities by the Laboratory Medical Director. 'p. Qualifies as the Technical Consultant, General Supervisor, and Testing personnel under CLIA regulations.'" 2. Review of the "Laboratory Supervisor" organizational job description revealed the educational requirement at Prairie Clinic is a Medical Technologist (MT) certification. 3. Review of the CMS209 personnel report revealed the laboratory supervisor has a Medical Laboratory Technician (MLT) certification. 4. Interview with staff A on April 17, 2023, at 12:45 PM confirmed the laboratory supervisor has a MLT certification and the laboratory director has not delegated responsibilities to a qualified individual per the organization's requirements.