

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393107	(X3) Date Survey Completed 04/30/2025
Name of Provider or Supplier Prairie Clinic	Street Address, City, State 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
D0000	A recertification survey of this laboratory was completed on April 30, 2025, the laboratory was found to be out of compliance with the CLIA regulations. The conditions not met include: D 6000 - 42 C.F.R. 493.1407 Condition: Moderate Complexity Laboratory Director D 6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant - Moderate Complexity
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures, competence evaluation records and interview with the Laboratory Supervisor (Staff A), the laboratory did not follow their procedures to evaluate the competence of one of one technical consultant. Findings include: 1. The 'Competency Assessment Procedure for Staff' stated, "Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC)...". 2. Review of competence evaluation records showed no evidence the laboratory evaluated the performance of the technical consultant in fulfilling their responsibilities. 3. Interview with Staff A on April 30, 2025, at 12:05 PM confirmed the laboratory had not documented evaluation of the technical consultant and confirmed they did not follow written procedures.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using</p>

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 surveyor review of laboratory records and interview with the Laboratory Supervisor (Staff A), the laboratory did not perform calibration verification for sodium, potassium, and chloride testing performed on the Dimension Xpand chemistry analyzer every six months in one of the last two years. Findings include: 1. Review of laboratory calibration verification records showed the laboratory performed calibration verification testing for sodium, potassium, and chloride testing on the Dimension Xpand chemistry analyzer on June 19, 2023, December 20, 2023, August 13, 2024, and March 3, 2025. 2. Interview with Staff A on April 30, 2025, at 1:15 PM confirmed the laboratory did not perform calibration verification within six months of the calibration verifications completed on December 20, 2023, or the August 13, 2024, events. This is a repeat deficiency previously cited on May 23, 2017.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
 Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form 209), procedures, and laboratory records, and interview with the Laboratory Supervisor (Staff A), the director did not provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The director delegated responsibilities to staff that did not meet the qualification requirements to perform the delegated responsibilities. See D6004. This is a repeat deficiency. 2. The director did not ensure the competence evaluation procedures evaluated the six elements required for competence evaluation for all staff performing non-waived testing. See D6030. 3. The director did not delegate in writing the testing responsibilities of each testing personnel and did not identify which personnel could report test results without review. See D6032.

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 reappropriates 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 surveyor review of procedures, the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form 209), and academic credentials and interview with the Laboratory Supervisor (Staff A), the Laboratory Director delegated responsibilities that must be performed by a laboratory director, technical consultant, or clinical consultant to the Laboratory Supervisor who did not meet the qualification requirements for a laboratory director or clinical consultant and did not meet the qualification requirements as a technical consultant prior to December 28, 2024. Findings include: 1.a. The procedure, 'Delegation of Duties', showed the Laboratory Director delegated the responsibilities at 493.1407(e)(1), (2), (3), (4), (5), (6), (7), (8), (9), (10), (11), (12), and (13) to the Laboratory Supervisor. 1.b. Review of the "Laboratory Supervisor Job Description" showed the position description included the above delegated job responsibilities and showed the position required Medical Technologist (MT) certification. 2. Review of the CMS Form 209 submitted for this survey and signed by the Laboratory Director on April 23, 2025, showed Staff A identified only as testing personnel. 3. Review of academic credentials showed Staff A held an associate's degree in medical laboratory technology. 4. Interview with Staff A on April 30, 2025, at 12:05 PM confirmed Staff A was not qualified to perform the responsibilities of a laboratory director or clinical consultant and did not meet the qualification requirements as a technical consultant prior to December 28, 2024. Further interview confirmed the director delegated responsibilities to Staff A when Staff A did not meet the qualification requirements to fulfill the responsibilities. This is a repeat deficiency previously cited on April 17, 2023.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures and competence assessment forms for testing personnel and interview with the Laboratory Supervisor (Staff A), the forms used for documenting competence evaluations did not ensure documentation of the required six elements for each test and included non-waived testing on the form the laboratory used to document waived testing competence. Findings include: 1. The "Competency

Assessment Procedure for Staff" includes the statement, "Use all six assessment methods for each test and methods were (sic) applicable." 2. Review of the laboratory's competence assessment forms showed the laboratory utilized two forms, "Competency Assessment Form Moderate Testing", and "Competency Assessment Form Waived Testing". 2.a. Review of the "Competency Assessment Form Moderate Testing" form showed the review of monitoring recording and reporting of results, blind testing of specimens, and troubleshooting or problem solving was not test specific. 2.b. Review of the waived testing form revealed the form included non-waived testing. The form included hematology testing and troubleshooting, potassium hydroxide (KOH) / wet prep, urine and post vasectomy microscopic examinations. The form did not document evaluation of the six elements required for competence evaluation for each non-waived test. 3. Interview with Staff A on April 30, 2025, at 12:05 PM confirmed the laboratory did not document each of the six required competence evaluation elements for each non-waived test performed in the laboratory and confirmed the form used to document competence for personnel performing waived testing included non-waived tests.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form 209) and laboratory competence evaluation forms and records and interview with the Laboratory Supervisor (Staff A), the laboratory did not have a written document identifying which examinations and procedures six of six non-degreed testing personnel were authorized to perform and whether review was required prior to reporting patient results. Findings include: 1. Review of the CMS Form 209 submitted for this survey and signed by the laboratory director on April 23, 2025, showed the laboratory employed two testing personnel, Staff A and B. The laboratory included a third individual, Staff E, with no laboratory role assigned. 2. During an interview with Staff A on April 30, 2025, at 9:30 AM, Staff A stated Staff E only performed and reported waived testing. 3. Review of completed "Competency Assessment Form Waived Testing" showed Staff A had documented competence evaluations for non-degreed Staff C, D, E, F, and G in 2024 and Staff G and H in 2023. The forms included non-waived tests including hematology testing and troubleshooting and potassium hydroxide (KOH) / wet prep, urine and post-vasectomy microscopic examinations and showed the identified staff were competent in performing the testing. 4. Interview with Staff A on April 30, 2025, at 12:05 PM confirmed non-degreed staff D, E, and G were currently employed and performed non-waived testing in the laboratory and revealed Staff E performed but did not report non-waived testing without review by another staff member. Staff A confirmed the director had not specified in writing which examinations and procedures each individual was authorized to perform and whether review was required for reporting results.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form 209) and laboratory records and interview with the Laboratory Supervisor (Staff A), the technical consultant did not provide technical oversight in accordance with 493.1413 of this subpart. Findings include: 1. The Technical Consultant did not evaluate or resolve potential technical problems with the Aspartate Aminotransferase (AST) test from December 2024 through March 2025. See D6043. 2. The Technical Consultant did not complete semi-annual competence evaluations for new staff during the first year of patient testing. See D6053. 3. The Technical Consultant did not complete annual competence evaluations for testing personnel. Testing personnel that did not meet the qualification requirements for technical consultant performed competence evaluations. See D6054.

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(5)

(b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications;

This STANDARD is not met as evidenced by:

Based on surveyor review of quality control records and interview with the Laboratory Supervisor (Staff A), the Technical Consultant did not evaluate the Unity Quality Control records to resolve technical problems and ensure remedial actions were taken when the reports showed the aspartate aminotransferase (AST) test standard deviation index (SDI) was not acceptable from December 2024 through March 2025, four of four months reviewed. Findings include: 1. Review of Unity Monthly Evaluation reports from December 2024 through March 2025 for Multiquel Controls, levels one and three, showed the report identified the AST test as a test that "may require investigation or review". The reports stated, "Warning: Acceptable values are above -2 and below 2." The following peer SDI results are from the Unity Reports, the laboratory added the corrective actions where noted. Unacceptable results are followed by a *. December 2024 Peer SDI for Control Level 1 2.01* Peer SDI for Control Level 3 2.40* No corrective actions documented; summary sheet not included in records. January 2025 Peer SDI for Control Level 1 2.37* Peer SDI for Control Level 3 2.87* Corrective Action: "watching, no obvious reason for this" February 2025 Peer SDI for Control Level 1 1.85 Peer SDI for Control Level 3 2.68* No correction Action documented March 2025 Peer SDI for Control Level 1 2.04* Peer SDI for Control Level 3 2.70* Corrective Action: "Recal on 3/26/25" 2. Interview with Staff A on April 30, 2025, at 1:15 PM confirmed the technical consultant had not evaluated the AST quality control reports to ensure the test system was functioning as expected and did not ensure the laboratory took remedial actions when the peer SDI continued to show unacceptable results identifying potential issues with the test system.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form 209) and competence assessment records and interview with the Laboratory Supervisor (Staff A), the technical consultant did not evaluate competence of testing personnel twice annually during the first year for four of four new testing personnel who performed non-waived patient testing. Findings include: 1. Review of the CMS Form 209 submitted for this survey and signed by the laboratory director on April 23, 2025, showed the laboratory had two testing personnel performing non-waived testing, Staff A and Staff B. 2. Review of the "Competency Assessment Form Waived Testing" forms for 2024 evaluations showed the form included the following non-waived tests: Hematology testing and troubleshooting and microscopic evaluations for urine, potassium hydroxide (KOH) / wet prep, and post vasectomy samples. The form documented evaluation of the six required competence evaluation elements in aggregate and did not show the technical consultant evaluated each of the elements for each non-waived test. The forms showed completed evaluations for four new testing personnel in 2024. No evaluations were evident for the four testing personnel in 2023, no second evaluations were evident in 2024 for these four testing personnel. The competence assessment forms for 2024 showed assessment of the following non-waived tests for: Staff C: Hematology and troubleshooting, urine microscopies, KOH / wet preps, and post vasectomy. Staff D: Hematology and troubleshooting, urine microscopies, KOH / wet preps, and post vasectomy. Staff E: Hematology and troubleshooting, KOH / wet preps, and post vasectomy. Staff F: Hematology. Included note, "Now works on nursing floor 9/1/2024". 3. Interview with Staff A on April 30, 2025, at 12:05 PM revealed staff C started working in the laboratory in May 2023, staff D in June 2023, Staff E in November 2023, and Staff F in April 2023. Further interview revealed hematology testing included testing samples with the Sysmex hematology analyzer and running and evaluating quality control samples. Staff A also confirmed the technical consultant did not complete semi-annual competence evaluations for new non-waived testing personnel during the first year of patient testing.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form 209) and competence evaluation records from 2023 and 2024 and interview with the Laboratory Supervisor (Staff A), the technical consultant did not document a 2023 annual competence evaluation for Staff B, one of two testing personnel identified on the CMS Form 209 submitted for this survey, and did not evaluate the competence of Staff A, the second testing personnel. Findings include: 1. Review of the CMS Form 209 submitted for this survey and signed by the

Laboratory Director on April 23, 2025, showed the laboratory identified two testing personnel who performed non-waived testing. 2. Review of competence evaluation records for the two identified testing personnel showed no documentation of competence evaluation for Staff B in 2023. 3. Review of the competence evaluation record from 2024 for Staff A showed competence evaluation was not performed by the Technical Consultant. 3.a. The "Examiner" column on the form showed the following staff completed non-waived evaluations. Chemistry: Staff B Hematology: Staff F and Staff E Urine, KOH / Wet prep, and Post vasectomy microscopics: Staff B 3.b. The following evaluations were not test specific and were completed as an aggregate for all tests by the identified staff. Staff H and F evaluated the monitoring of recording and reporting results. Staff D and F evaluated review of quality control, proficiency testing, and preventative maintenance records. Staff B and H performed direct observation of instrument maintenance for the chemistry and hematology analyzers. Staff F and G assessed testing performance through proficiency testing and internal blind testing. Staff B assessed problem solving skills. 4. Interview with Staff A on April 30, 2025, at 12:05 PM confirmed records showing the annual evaluation of competence for Staff B in 2023 was not available and confirmed the technical consultant had not performed the competence evaluation for Staff A in 2024. Further interview confirmed competence evaluations were completed by staff that did not meet the qualification requirements for technical consultant.