

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0911694	(X3) Date Survey Completed 03/25/2026
Name of Provider or Supplier Wildwood Family Clinic Sc	Street Address, City, State 251 East Cottage Grove Rd, Cottage Grove, 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 was completed on March 25, 2026. The laboratory was found out of compliance with the CLIA regulations. The laboratory failed to meet the following conditions, resulting in initial unsuccessful PT participation: D2016 - 42 C. F.R. 493.803 Condition: Successful Participation [proficiency testing] D6000 - 42 C. F.R. 493.1403 Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of records from the Certification and Survey Provider Enhanced Reporting (CASPER) reports and American Proficiency Institute (API)</p>

proficiency testing (PT) reports, and interview with the Laboratory Director, the laboratory failed to successfully participate in a PT program approved by Centers for Medicare and Medicaid Services (CMS), for each analyte or test in which the laboratory is certified under Clinical Laboratory Improvement Amendments (CLIA). The laboratory failed to successfully participate in total protein analyte testing in the subspecialty of routine chemistry. Refer to D2096.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on surveyor review of records from the Certification and Survey Provider Enhanced Reporting (CASPER) reports and American Proficiency Institute (API) 2025 and 2026 proficiency testing (PT) reports, and interview with the Laboratory Director, the laboratory failed to achieve satisfactory performance (80%) for total protein analyte testing in two of two consecutive testing events in the subspecialty of routine chemistry. Findings included: 1. Review of the CASPER 0155 report revealed the following results: Routine Chemistry 2025 3rd Event: The laboratory received an overall unsatisfactory score for the subspecialty of 0%, which included a score of 0% for total protein. Routine Chemistry 2026 1st Event: The laboratory received an unsatisfactory score of 20% for total protein. 2. Review of the API reports and records in the laboratory during the recertification survey from the two most recent PT events confirmed the findings on the CASPER report, revealing the following: The API "Performance Summary 2025 Chemistry - Core 3rd Event" report showed the laboratory received 0% in routine chemistry, including for the total protein analyte, for the third PT event in 2025. The API "Performance Summary 2026 Chemistry - Core 1st Event" report showed the laboratory received 20% for the total protein analyte. The API "Comparative Evaluation 2026 Chemistry - Core - 1st Event" report included the columns, in part, Sample / Reported Result / Expected Result / Performance. The results for the total protein analyte samples were as follows: CH-01 / 5.6 / 5.7-6.8 / Unacceptable CH-02 / 2.4 / 2.4-3.0 / Acceptable CH-03 / 9.2 / 9.3-11.0 / Unacceptable CH-04 / 4.0 / 4.1-4.9 / Unacceptable CH-05 / 8.4 / 8.8-10.4 / Unacceptable 3. During an interview with the Laboratory Director on March 25, 2026, at 12:11 PM, the Laboratory Director confirmed the laboratory did not successfully participate in PT for the total protein analyte in two of two consecutive testing events in the subspecialty of routine chemistry, and confirmed understanding that this is a mandatory PT deficiency.

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 records from the Certification and Survey Provider

Enhanced Reporting (CASPER) reports and American Proficiency Institute (API) proficiency testing (PT) reports, and interview with the Laboratory Director, the Laboratory Director failed to provide overall management and direction of the laboratory services. The Laboratory Director failed to ensure the laboratory tested and reported PT samples as required. Refer to D6016 and D6017.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor review of records from the Certification and Survey Provider Enhanced Reporting (CASPER) reports and American Proficiency Institute (API) 2025 and 2026 proficiency testing (PT) reports, and interview with the Laboratory Director, the Laboratory Director failed to ensure successful participation for total protein analyte testing in a Centers for Medicare and Medicaid Services (CMS) approved PT program. Refer to D2096.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

(e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program;

This STANDARD is not met as evidenced by:

Based on surveyor review of records from the Certification and Survey Provider Enhanced Reporting (CASPER) reports and American Proficiency Institute (API) proficiency testing (PT) records, and interview with the Laboratory Director, the Laboratory Director failed to ensure the laboratory returned PT results within the timeframes specified by the PT program for nineteen of nineteen regulated analytes in the API 2025 Chemistry - Core third event. Findings include: 1. Review of the CASPER 0155 report revealed the following results: Routine Chemistry 2025 3rd Event: The laboratory received an overall unsatisfactory score for the subspecialty of 0%, which included 0% scores for alanine aminotransferase (SGPT), albumin, alkaline phosphatase (alk phos), aspartate aminotransferase (SGOT), total bilirubin (bili, total), total calcium (CA, total), carbon dioxide, chloride (Cl), total cholesterol (cholesterol, total), high density lipoprotein cholesterol (cholesterol, HDL), low density lipoprotein cholesterol (cholesterol, low density lipoprotein, direct measu), creatinine, glucose (glucose, non-waived), potassium (K), sodium (Na), total protein, triglyceride (trigl), urea nitrogen (BUN), and uric acid. 2. Review of the API "2025 Chemistry - Core 3rd Event Performance Summary" confirmed the finding in the CASPER 0155 report. 3. Review of records in the laboratory during the recertification survey revealed the laboratory had completed the API "Performance Review and Corrective Action Documentation, 2025 Chemistry - Core - 3rd Event" form which stated in part, "Received 0% because results were entered but not submitted." 4. Interview with the Laboratory Director on March 25, 2026, at 12:11 PM confirmed the laboratory failed to submit any of the results for the 2025 Chemistry - Core third PT event to API before the specified due date, confirming the Laboratory Director failed to ensure the laboratory returned PT results within the timeframes specified by

the PT program for the nineteen of nineteen regulated analytes in the subspecialty of routine chemistry.