Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 52D0911694	**(X3) Date Survey Completed** 03/13/2024
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with Testing Personnel (Staff A), the laboratory did not document the duplicate testing and reporting of five of five chloride tests during the second chemistry event in 2023. Findings include: 1. Review of PT records showed two sets of chloride results for the five samples in the 2023 second chemistry event. The records showed personnel performed all chemistry tests, including chloride tests, on May 30, 2023, and showed personnel repeated chloride testing of the five samples on June 5, 2023. The laboratory reported the June 5, 2023, chloride results to the proficiency testing provider. The records showed no documented reason for the repeated chloride testing on June 5, 2023. 2. Interview with Staff A on March 11, 2024, at 11:15 AM confirmed there was no documentation of the need for repeat testing of the chloride results or the reason for reporting the results from June 5, 2023, instead of the results from May 30, 2023.
D3031	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of pediatric bilirubin control records and manufacturer's instructions and interview with Testing Personnel (Staff A), the laboratory did not document and retain the lot number of control material in use for two of two pediatric bilirubin control levels in 2022 or 2023. Findings include: 1. Review of the control logs, 'Neonatal Bilirubin Control Data', showed the forms included a space to record the lot numbers of control level 1 and 2. Personnel had not entered the lot numbers on the forms during 2022 or 2023. 2. Review of the manufacturer's instructions provided by Staff A for the Quantimetrix Bilirubin Control Pediatric / Level 1 & 2 showed the instructions were specific for lot numbers 22571 & 22572. The insert showed no indication of when the laboratory started using lot numbers 22571 and 22572. 3. Interview with Staff A on March 11, 2024, at 12:45 PM confirmed personnel had not documented the lot number of control material used on the log and confirmed the laboratory had not retained documentation showing the lot number of the pediatric bilirubin controls in use for at least two years.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) reports, procedures, and laboratory records and interviews with the laboratory director and Testing Personnel (Staff A), the laboratory did not review the effectiveness of corrective actions taken for unacceptable neonatal direct bilirubin results in six of seven PT events from 2022 through 2024. Findings include: 1. Review of PT reports showed the following results for Bilirubin, Direct (Neonatal), results shown in mg/dL (milligrams per deciliter). Event Score Sample reported result / acceptable range 2022-01 50% NB-02 10.5 / 4.9 - 10.4 2022-02 100% NB-06 9.6 acceptable result NB-07 8.4 acceptable result 2022-03 50% NB-12 13.5 / 5.3 - 10.5 2023-01 50% NB-01 12.6 / 4.5-10.3 NB-02 not graded (no consensus) 2023-02 0% NB-06 3.7 / 1.1 - 3.6 NB-07 15.2 / 5.3-10.9 2023-03 50% NB-12 11.0 / 4.1 - 9.1 2024-01 50% NB-01 10.8 / 4.5 - 8.8, NB-02 not graded (no consensus) 2. Review of the 'Neonatal Bilirubin Procedure' showed, "D. bilirubin results over 8.0 mg/dL will be sent to reference laboratory." 3. Review of laboratory PT records showed staff stated in the "Performance Review and Corrective Action" section of the 2023 event three report, "This specimen would have been sent to our reference lab because we don't report any result out 8.0 or higher." The laboratory documented similar statements for other events with unacceptable results. The records showed no evidence staff identified the repeat failures for neonatal direct bilirubin testing and no evidence of review of the identified corrective actions. 4. Interview

	with the laboratory director on March 11, 2024, at 2:00 PM confirmed the corrective actions taken did not address the unacceptable results from the proficiency testing program and confirmed the laboratory did not complete reviews of the corrective actions taken. In an email interview on March 13, 2023, at 11:33 AM, Staff A stated the laboratory does not have an orderable code for on-site neonatal direct bilirubin testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory maintenance records for the Horiba ABX Pentra 400C and interview with Testing Personnel (Staff A), staff did not replace the chloride electrode every four months as required; one of the last four replacements was due in May and completed in June. Findings include: 1. Review of laboratory maintenance records for the Horiba ABX Pentra 400C chemistry analyzer showed the manufacturer required replacement of the chloride electrode every four months. The maintenance logs showed staff replaced the electrode on January 13, 2023, and did not replace the electrode again until June 5, 2023. 2. Interview with Staff A on March 11, 2024, at 2:15 PM confirmed staff should have replaced the chloride electrode by May 13, 2023, and confirmed the laboratory did not perform maintenance as required by the manufacturer.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of pediatric bilirubin control records and manufacturer's instructions and interview with Testing Personnel (Staff A), the laboratory did not define statistical parameters for each lot number of two of two levels of control material and the laboratory could not demonstrate they evaluated statistical parameters over time or documented concurrent testing of new control materials with previously determined statistical parameters after September 27, 2022. Findings include: 1. Review of the control logs, 'Neonatal Bilirubin Control Data', showed the forms

	included areas for documenting the calculated mean (average), range (acceptable result range), SD (calculated standard deviation), and CV (calculated coefficient of variation). The December 2023 form showed the level two control acceptable range was 19-21, previous forms showed the acceptable range was 19 - 22. The laboratory did not document a reason for the change. Review of the forms from 2022 and 2023 also showed personnel had not entered data for the calculated mean, SD, and CV. Records showed evaluation of control ranges on July 8, 2022. The laboratory determined the acceptable control range for level one was 11 - 13 mg/dL (milligrams /deciliter) and the acceptable range for level two was 22-24 mg/dL. Additional records showed testing of QC material on September 27, 2022; these records did not identify the lot numbers of the controls or the calculated mean or ranges. Review of records from 2023 showed no evaluation of control mean or acceptable ranges. 2. Review of the manufacturer's instructions provided by Staff A for the Quantimetrix Bilirubin Control Pediatric / Level 1 & 2 showed the instructions were specific for lot numbers 22571 & 22572. The insert showed no indication of when the laboratory began using product in use in the laboratory. Further review of the insert showed Quantimetrix provided statistical parameters including the expected mean and range results for six analyzers. The insert included no data for the Horiba ABX Pentra C400 used by staff for bilirubin testing. 3. Interview with Staff A on March 11, 2024, at 12:45 PM confirmed personnel had not defined statistical parameters for each lot of control material used and confirmed the laboratory had not evaluated the statistical parameters over time.