Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0911694	(X3) Date Survey Completed 04/04/2022
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) corrective action plans and laboratory procedures and interview with the clinic supervisor, staff A, the laboratory did not revise the "Neonatal Bilirubin" procedure to include referral information. Findings include: 1. Review of American Proficiency Institute (API) "Performance Review and Corrective Action" for PT event 2021 Chemistry-Core-3rd Event showed corrective action for unsuccessful performance in Bilirubin, Direct (Neonatal) was determined to be "any abnormally high results would be confirmed by the reference laboratory. Further review showed the laboratory director signed this corrective action

	on November 2, 2021. 2. Review of the "Neonatal Bilirubin" procedure showed no revision date after the initial approval date of May 8, 2018. Further review confirmed no revision for referral of specimens was included in the procedure. 3. Interview with staff A on April 4, 2022 at 10:45 AM confirmed the laboratory did not revise the "Neonatal Bilirubin" procedure to include referral information per corrective action on the API PT review of results for 2021 Chemistry-Core-3rd Event.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records and quality assurance plan (QAP) reports and interview with the clinic supervisor, staff A, the technical consultant (who is the laboratory director) did not review and evaluate the chemistry QC to ensure the QC program was maintained to assure acceptable levels of test performance for twelve of twelve months in 2021. Findings include: 1. Review of chemistry QC for 2021 showed no evidence the technical consultant (who is the laboratory director) reviewed and evaluated the daily chemistry QC records. 2. Review of monthly chemistry QAP reports for 2021 showed no evidence the technical consultant (who is the laboratory director) reviewed the chemistry QAP reports for 2021 for twelve of twelve months. Further review showed the technical consultant (who is the laboratory director), reviewed and evaluated the monthly QAP reports for 2021 on February 22, 2022. 3. Interview with staff A on April 4, 2022 at 10:45 AM confirmed the technical consultant (who is the laboratory director) did not review and evaluate the chemistry QC to ensure the QC program was maintained to assure acceptable levels of test performance for twelve of twelve months in 2021.