Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393727	09/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Wildwood Family Clinic	4901 Cottage Grove Rd, Madison, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with Testing Personnel (Staff A), the laboratory did not define the acceptable humidity requirements and did not document the room temperature or humidity to ensure appropriate storage of reagents and reliable operation of the analyzers in the laboratory for the last two of two years. Findings include: 1. Review of laboratory records showed no documentation of the room temperature or humidity in the laboratory. 2. Review of the procedure, "Daily Laboratory Quality Control", showed the procedure required daily documentation of the room temperature between 20 - 26 degrees C (Celsius). Further review showed no evidence the laboratory evaluated the humidity requirements for the test systems in the laboratory. 3. Interview with Staff A on September 5, 2024, at 11:50 AM confirmed staff did not monitor or document the room temperature and humidity in the laboratory.
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 laboratory records and interview with testing personnel, the laboratory director, who is also the technical consultant, did not provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The laboratory director did not ensure the quality control program was established and maintained for the Pentra C400 analyzer to identify issues with the test system when they occurred in December 2023. See D 6020. 2. The laboratory director did not ensure testing personnel did not report patient test results when the Pentra C400 test system was not functioning properly. See D 6025.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records from the Pentra C400 analyzer and procedures and interview with Testing Personnel (Staff A), the director did not ensure the quality control program for the Pentra C400 was established and maintained to allow testing personnel to identify issues with the test system as they occurred on six of six days in December 2023. Findings include: 1. Review of the 'Monthly QC results December 2023' and the 'Current Worklist QC Results' records for December 18 through 22 and 26, 2023, showed testing personnel performed multiple repeated testing runs over several days for each the following six analytes. The number of runs on each day with each control is shown below. The report identified the two external controls as 'N Multicontrol' and 'P Multicontrol'. Glucose: Level N Multicontrol December 18, 2 runs December 19, 3 runs December 20, 5 runs Level P Multicontrol December 20, 2 runs Potassium: Level N Multicontrol December 18, 5 runs, no acceptable result December 19, 3 runs Level P Multicontrol December 18, 5 runs, no acceptable result December 19, 2 runs December 21, 2 runs Chloride: Level N Multicontrol December 18, 5 runs, no acceptable result Level P Multicontrol December 18, 5 runs, no acceptable result December 21, 2 runs Sodium: Level P Multicontrol December 18, 5 runs, no acceptable result December 21, 2 runs High Density Lipoprotein (HDL) Level N Multicontrol December 21, 3 runs December 22, 2 runs December 26, 5 runs Low Density Lipoprotein (LDL) Level N Multicontrol December 22, 4 runs, no acceptable result December 26, 9 runs Level P Multicontrol December 26, 6 runs The 'Current Worklist QC Results' Daily control report showed the following corrective actions: December 18: Re-ran ISE (Ion selective electrode) control after cleaning. The report showed no corrective actions for the glucose control. December 19: Glucose reran / replace / recalibrate. The report showed no corrective action for the potassium control. December 20: Calibrate and reran the glucose. December 21: The report showed no documented corrective actions. December 22: Calibrate and re-ran LDL replaced and re-ran LDL. The report showed no corrective actions for the HDL control. December 26: Calibrate and reran

	HDL and LDL The documented corrective actions did not show the laboratory evaluated patient testing performed since the last acceptable QC results to ensure accuracy of the reported results. The 'Monthly QC results December 2023' reports showed shifts in the QC values for each of the six analytes above during December 2023. No review of the shifted results is evident on the reports. 2. The "Quality Control Operation" Policy (LAB-166-1) stated, "It is unexpected for the control results to exceed a control limit or violate a control rule unless there is a problem with the testing process." The "Quality Control Process & Implementation" (SOP LAB-333-1) stated in the policy section, "Shifts and Trends must be noted and documented as to cause and correction on the quality control log sheets". Step 10 of the procedure stated, "When control results are "out-of-control", reject the run and do not report patient test results. Inspect the process, identify the source of difficulty, correct the problem, and then reanalyze the controls." Step 12 directed staff to document any control/calibration problems and excluded testing and to document what was done to solve them on the daily QC for the affected analyte/control. 3. Interview with Staff A on September 5, 2024, at 2:30 PM confirmed documentation of corrective actions was not complete, and the quality control program was not maintained to ensure quality of testing.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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. (e) The laboratory director must-- (e)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on surveyor review of quality control records and interview with Testing Personnel (Staff A), the laboratory director did not ensure testing personnel did not report patient test results when the Pentra C400 test system was not functioning properly on two of two days quality control (QC) results were not acceptable in December 2023. Findings include: 1. Review of the 'Current Worklist QC Results' from December 18, 2023, showed the laboratory did not obtain acceptable results for potassium and chloride testing with level N or level P controls. Additionally, the laboratory did not obtain acceptable sodium results with the Level P control. Review of the 'Current Worklist QC Results' report from December 22, 2023, showed the laboratory did not obtain acceptable results for LDL (Low Density Lipoprotein) testing with the Level N control. 2. Interview with Staff A on September 5, 2024, at 2: 30 PM confirmed the Pentra C400 test system was not functioning properly when the laboratory did not obtain acceptable control results. Email correspondence with Staff A on September 18, 2024, at 8:31 AM revealed the laboratory reported six patient sodium, potassium and chloride results on December 18, 2023, and the laboratory reported four patient LDL results on December 22, 2023, when control results were not acceptable.
D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure

	that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of personnel records and interview with Testing Personnel (Staff A), the laboratory did not document training of one of one new Testing Personnel (Staff B) to ensure Staff B had the skills and knowledge required to ensure accurate testing. Findings include: 1. Review of personnel records for Staff B showed the laboratory director completed initial competence evaluations in February 2024. The records showed no documentation of training for each moderate complexity test system in the laboratory. 2. Interview with Staff A on September 5, 2024, at 9:37 AM confirmed the laboratory did not document training for Staff B.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, the manufacturer instructions and the laboratory procedure and interview with Testing Personnel (Staff A), testing personnel did not follow the laboratory's procedure for negative external control testing for five of the last five AmniSure ROM (Rupture of (fetal) Membranes) Tests. Findings include: 1. Review of the laboratory test logs for AmniSure ROM Tests showed testing personnel used water for the negative control for the last five AmniSure ROM tests. 2. Review of the Manufacturer's instructions for the AmniSure ROM Test showed, "Saline solution is recommended for negative external control." The instructions did not address the use of water as the negative control. 3. Review of the laboratory procedure, "AmniSure Rupture of Fetal Membrane (ROM) Test" showed the laboratory used AmniSure Solvent Solution as the external negative control. 4. Interview with Staff A on September 5, 2024, at 2:30 PM confirmed testing personnel did not follow the manufacturer's instructions or the laboratory procedure when they used water for the negative external control for the AmniSure ROM Test.