Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393727	11/07/2022
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
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Item 1 Based on surveyor review of Pentra C400 chemistry quality control records and laboratory records and interview with the laboratory lead, staff A, testing personnel did not document corrective actions taken when quality control (QC) did not meet the laboratory's specifications. Findings include: 1. Review of the Pentra C400 QC for September 2022 showed the following analytes with unacceptable QC results on the following dates: September 23, 2022: Alkaline phosphatase: QC was performed eight times between 8:44 AM and 11:45 AM, with seven of eight QC results being excluded from the data points. Carbon Dioxide: QC was performed six times between 8:42 AM and 11:11 AM, with five of six QC results being excluded from the data points. Blood Urea Nitrogen: QC was performed six times between 8:42 AM and 11:11 AM, with five of six QC results being excluded from the data points. September 30, 2022: Sodium: QC was performed two time, with one of two QC results being excluded from the data points. Potassium: QC was performed two time, with one of two QC results being excluded from the data points. 2. Review of laboratory records showed no evidence of a corrective action log or corrective action documentation for the QC that was excluded from the data points in September 2022.

	3. Interview with staff A on November 7, 2022, at 12:10 PM confirmed testing personnel did not document corrective actions taken when quality control (QC) did not meet the laboratory's specifications on the Pentra C400 chemistry analyzer. Item 2 Based on surveyor review of ABX Micros 60 hematology analyzer quality control records and laboratory records and interview with the laboratory lead, staff A, testing personnel did not document corrective actions taken when quality control (QC) did not meet the laboratory's specifications. Findings include: 1. Review of the ABX Micros 60 QC for November 2022 showed level three of the QC was rerun three times on November 2, 2022. 2. Review of laboratory records showed no evidence of a corrective action log or corrective action documentation for the QC that was rerun in November 2022. 3. Interview with staff A on November 7, 2022, at 12:10 PM confirmed testing personnel did not document corrective actions taken when quality control (QC) did not meet the laboratory's specifications on the ABX Micros 60 hematology analyzer.