Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2053190	12/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Metrolina Nephrology Associates Laboratory	3158 Freedom Drive Suite 3101, Charlotte, NC	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based upon review of 2022 and 2023 calibration verification records and interview with the TC (Technical Consultant) on 12/11/23, the laboratory failed to perform calibration verification activities that included a minimum value near the lower limit of the laboratory's reportable range for 1 of 2 analytes performed on its Centaur immunology instrument. Findings: Review of the November 2023 calibration verification records for Vitamin D performed on the Centaur instrument revealed the

	following data: Five concentrations of linearity material were used to assess the reportable range of Vitamin D. These five samples demonstrated the following means: 24.2 ng/mL, 65.35 ng/mL, 101.187 ng/mL, 133.32 ng/mL, 147.35 ng/mL Review of the May 2023 calibration verification records for Vitamin D performed on the Centaur instrument revealed the following data: Five concentrations of linearity material were used to assess the reportable range of Vitamin D. These five samples demonstrated the following concentrations: 26.16 ng/mL, 66.86 ng/mL, 103.793 ng/mL, 130.637 ng /mL, 145.945 ng/mL In interview at approximately 12:10 p.m., the TC checked the Orchard LIS (laboratory information system) and confirmed the laboratory reports Vitamin D values within a range of 4.2-150 ng/mL.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based upon the review of 2022 and 2023 quality assessment records and interview with the TC (Technical Consultant) on 12/11/23, the laboratory failed to check the accuracy of all calculations performed by the Orchard LIS (laboratory information system) to produce patient results. The laboratory performs approximately eleven calculations. Findings: The review of quality assessment records revealed the absence of documents to confirm the accuracy of calculations performed by the Orchard LIS. The LIS utilizes patient laboratory values and other chart information to calculate additional test results that are reported to the patient's provider. In interview, at approximately 1:30 p.m., the TC stated the laboratory does not check calculations performed by the LIS.