Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0318753	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier Louisville Medical Clinic	**Street Address, City, State** 14724 Highway 15 North, Louisville, MS	

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 on review of calibration and calibration verification records for the Siemens Dimension EXL 200 chemistry analyzer since it was installed in November 2021 and interview with the technical consultant on 2/7/2023 at 3:30 p.m., the laboratory failed to perform calibration verification at least once every six months for sodium, potassium, and chloride testing since November 2021. Findings include: Review of calibration records for the Siemens Dimension EXL 200 chemistry analyzer since

	installation in November 2021 revealed the sodium, potassium, and chloride tests have only two levels of calibrator. There was no documentation available on 2/7/2023 of calibration verification performed on sodium, potassium, and chloride tests since the initial calibration verification in November 2021. In an interview on 2/7/2023 at 3: 30 p.m., the technical consultant confirmed calibration verification had not been performed on sodium, potassium, and chloride testing since the initial verification in November 2021.