

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0316773	(X3) Date Survey Completed 01/14/2025
Name of Provider or Supplier Bolivar Phys Pract Db a Cleveland Medical Clinic	Street Address, City, State 810 East Sunflower Road Ste 100-A, Cleveland, 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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of Siemens Dimension EXL 200 records to include assay package inserts, calibration records from installation and confirmation from the laboratory manager, the laboratory failed to perform calibration verification at least every 6 months for Sodium (Na), Potassium (K), and Chloride (Cl) for three of three six-month periods. Findings include: 1. Review of the Siemens Dimension manufacturer's calibration package insert sheet list that Na, K, and Cl are calibrated using less than 3 calibration materials. Calibration verification is required every 6 months on assays that are calibrated with less than 3 calibrator levels. 2. Review of the Siemens Dimension EXL 200 calibration records revealed no documentation of</p>

calibration verification on Na, K, and Cl since installation on 7/11/2023. Three of three six-month calibration verifications were not available on the day of survey. 3. The laboratory manager confirmed in an interview on 1/14/2025 at 5:00 p.m. that calibration verifications had not been performed for Na, K, and Cl on the Siemens Dimension EXL 200 since instrument installation.