

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0249810	(X3) Date Survey Completed 02/16/2022
Name of Provider or Supplier Southernmed Pediatrics- Northeast At Farrow	Street Address, City, State 120 Highland Center Drive, Columbia, SC	
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>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.</p> <p>This STANDARD is not met as evidenced by: This STANDARD is not met as evidenced by: During an onsite recertification survey on 02/16/2022, based on a review of Horiba operator ' s guide, calibration record review, and staff interview, it was determined that the staff failed to ensure that a calibration was performed on the analyzer at least every six months as required by the manufacturer for 9 out of 24 months reviewed a. March 2021 b. April 2021 c. May 2021 d. June 2021 e. July 2021 f. August 2021 g. September 2021 h. October 2021 I.</p>

November 2021 J. December 2021 K. January 2022 Findings Include: 1. A review of the Horiba operator ' s guide revealed that a calibration should be performed at least every six months. 2. An onsite review of Horiba calibration records revealed that the following months were not available to review at the time of survey (9 out of 24 months) a. March 2021 through January 2022 3. Testing personnel confirmed during an onsite interview on 02/16/2022 at 9:45am that no calibration records were available for 9 out of 24 months at the time of survey.