

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0683117	<b>(X3) Date Survey Completed</b>  11/12/2025
<b>Name of Provider or Supplier</b>  Shelbyville Pediatrics	<b>Street Address, City, State</b>  71 Mack Walters Road, Shelbyville, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on 11/12/2025. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 direct observation, policy review, calibration records, and confirmed in interview, the laboratory failed to perform 6 month calibration verification for 2 out of 3 events observed. The findings included: During a tour of the laboratory on 11/12 /2025 at 10:50 AM, a Medonic M Hematology Analyzer, Serial Number 26442, was observed. Review of the policy procedure in the section labeled Medonic M, (revised</p>

date not documented) stated: "Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months." Review of the calibration records revealed the following: May 2024 - calibration performed November 2024 - no documentation May 2025 - no documentation During an interview on 11/12/2025 at 11:40 a.m. in the office area next to the laboratory, the Technical Consultant (TC) was asked to provide documentation for 6 month calibration. Documentation was not provided. This confirmed the findings.