

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0683117	(X3) Date Survey Completed 04/18/2019
Name of Provider or Supplier Shelbyville Pediatrics	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview, and review of the Procedure Manual for the Cell Dyn Emerald Hematology analyzer on April 18, 2019 at 2:35 PM, the laboratory failed to perform and document calibration procedures in accordance with manufacturer's instructions. Findings include: 1. Review of the Procedure Manual for the Cell Dyn Emerald Hematology analyzer revealed calibration should be performed at least every six (6) months. 2. Record review revealed there was no documented evidence the laboratory performed calibration verification between April 18, 2017 through April 17, 2019. 3. Testing personnel acknowledged in an interview on 04/18/2019 at 2:35 PM , the laboratory failed to have a system in place to ensure calibration of the Cell Dyn Emerald analyzer be performed and documented in accordance with manufacturer's requirements.</p>