

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 25D2053253	<b>(X3) Date Survey Completed</b> 10/01/2020
<b>Name of Provider or Supplier</b> Jfmc Ellisville Llc	<b>Street Address, City, State</b> 85 Hal Crocker Rd, Ellisville, MS	
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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 review of the Hematology Policy and Procedure Manual, the calibration log printed from the Clinical Diagnostics Solutions (CDS) Medonic M-Series hematology analyzer, and lack of documentation of calibration, the laboratory failed to perform and document calibration of the CDS Medonic M-Series hematology analyzer every six months, according to manufacturer's instructions. Findings include: Review of the Hematology Policy and Procedure Manual revealed the manufacturer's instructions state that calibration of the CDS Medonic M-Series hematology analyzer should be performed every six months and after any major maintenance. On the day of the survey, 10/1/20, there was no documentation of calibration of the hematology analyzer since 1/4/19. Review of the calibration log printed from the CDS Medonic M-Series hematology analyzer revealed the last calibration was 1/4/19.</p>