

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0920583	(X3) Date Survey Completed 09/14/2021
Name of Provider or Supplier Lebonheur Pediatrics Llc	Street Address, City, State 871 Ridgeway Loop Rd Ste 200, Memphis, TN	
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 review of survey documentation, instrument calibration records, manufacturer operator's manual and interview with the technical consultant, the laboratory failed to follow manufacturer's instruction for calibration in 2019 (one of five calibrations reviewed). The findings include: 1. Review of documentation provided during the remote survey revealed the Beckman Coulter AcT Diff complete blood count instrument in use for patient testing. 2. Review of calibration records for the Beckman Coulter AcT diff CBC instrument revealed a failed reproducibility for the hemoglobin analyte for the calibration performed on 12.30.2019. There was no documentation of corrective action for the failed reproducibility. 3. Review of the Beckman Coulter AcT Operator's Manual revealed the following: "If Reproducibility fails, contact your local Beckman Coulter Representative." 4. Interview on September 14, 2021 at approximately 10:35 am with the technical consultant confirmed the laboratory failed to follow manufacturer instructions for calibration when it did not contact the manufacturer regarding failed reproducibility check for calibration performed on 12.30.2019 (one of five calibrations reviewed).</p>