

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0888558	(X3) Date Survey Completed 05/17/2018
Name of Provider or Supplier Bbh Primary And Specialty Care Network	Street Address, City, State 4902 Valleydale Road, Birmingham, AL	
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 a review of calibration records, the manufacturer's instruction guide, and an interview with the Testing Personnel (TP) and Technical Consultant (TC), the laboratory failed to perform and document two calibrations in 2017, as required by the manufacturer. The findings include: 1. A review of the Medonic Hematology analyzer calibration records revealed calibrations were performed on 5/3/2016, 11/23/2016, and 2/24/2018 (fifteen months later). There was no documentation of calibrations performed in 2017. 2. The Medonic instruction guide in section 7 revealed calibrations should be performed every six months. 3. During an interview on 5/17 /2018 at 10:18 AM, the TP and TC reviewed the Medonic calibration records and confirmed that calibrations for 2017 were not performed because the standing order for the calibrators was discontinued. Jeremy Westry, BS, MT (ASCP) Licensure and Certification surveyor</p>