Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301738	09/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
University Medical Center	850 Peter Bryce Blvd, Tuscaloosa, 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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter DxH 600 Hematology analyzer calibration and quality control records, a review of the calibration procedure and an interview with the Technical Consultant, the laboratory failed to follow the manufacturer's instructions to verify the calibration by running quality controls (QC) afterwards for one out three 2017 calibrations of the Hematology analyzer. The findings include: 1. A review of the calibration records for the Beckman Coulter DxH 600 revealed the instrument was calibrated on 2/16/2017 at 2:04 PM. 2. A review of the QC records revealed controls for 2/16/17 were only run at 8:10 AM. 3. A review of the calibration guidelines in the binder revealed, under "Quality Assurance ... Calibration ... 12. Verify your calibration with controls. ..." (on page 3 of 6). 4. During an interview on 9/26/2018 at 3:40 PM, the Technical Consultant (TC) confirmed the testing personnel had failed to perform QC after the 2/16/2017 calibration. The TC then printed the "Result Listing Report" for 2/16/2017 from the LabDAQ Laboratory Information

	System, and stated 17 patient CBC's (Complete Blood Counts) had been performed after the calibration. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor