

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2063599	(X3) Date Survey Completed 02/04/2020
Name of Provider or Supplier Medcenter Hoover	Street Address, City, State 1575 Montgomery Highway, Hoover, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the calibration records, including the manufacturer's assay information sheets, for the Beckman Coulter Act-diff, and interviews with the office manager [also Testing Personnel (TP) #2], the surveyor determined the laboratory calibrated the analyzer, using an expired lot number of calibrator material. This affected one of five calibration records, reviewed by the surveyor. The findings include: 1. A review of the calibration records (the calibration report, precision, reproducibility, carryover) for the Beckman Coulter AcT diff revealed the analyzer was calibrated on February 14, 2018. Further review of the calibration records revealed an attached manufacturer's assay information sheet with the lot number 4734, which expired on 2/03/2018, several days prior to the date the calibration was performed. 2. In an interview on February 4, 2020 at 1:08 - 1:30 PM, the surveyor inquired of the use of the expired calibrator material and asked the office manager (TP #2) to review the records. After reviewing the calibration records, the office manager stated the calibration occurred prior to her employment with the laboratory and she would need to consult with a former employee. At 1:17 PM, during a telephone conversation with the former employee, TP #2 stated the staff, at the time of the calibration, realized the calibrator material had expired and was instructed to cease the calibration of the analyzer, until a new calibrator could be ordered. According to the former employee, the calibration had been re-done, using new calibrator material, obtained from Beckman Coulter. However, no additional documentation could be found showing the calibration was re-done with in-date calibrator material. The staff searched in other manuals/binders for additional documentation of a calibration,</p>

which might have been re-done, but did not find any additional documentation. At 1:25 PM, TP #2 spoke with the Technical Consultant, who instructed TP #2 to call Beckman Coulter for a confirmation of shipment of calibration material at or around the date in question. TP #2 called Beckman Coulter, however, the company did not have a record of transaction with the laboratory for new calibrator material around the time of the calibration in question.