

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0669755	(X3) Date Survey Completed 11/25/2019
Name of Provider or Supplier Drs Black & Benton, Psc	Street Address, City, State 4741 N Broadway, Knoxville, 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 a review of the Bilirubin Test Kit procedure, review of Bilirubin Standard results for patient tracers and upon interview with the Nurse Laboratory Manager, it was determined the daily bilirubin standards failed to be within the acceptable limits for 2018 and 2019. The findings include: 1. A review of the Bilirubin Test Kit procedure states to run the 5mg and 20mg standards each day of patient testing and the results should not drift more than (+/- 0.2mg/dl) daily. 2. A review of the Bilirubin Standard monthly results for patient tracers on dates: 4/12/18; 11/30/18; 1/25/19 and 8/12/19 were found not to be within the (+/- 0.2mg/dl) acceptable limits daily. 3. An interview at 12:15p.m. on November 25, 2019 with the Nurse Laboratory Manager confirmed the Bilirubin Standards were not within the acceptable limits upon review of patient tracers in 2018 and 2019. =====</p>