Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1021770	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jeffers, Mann & Artman Pediatric &	530 New Waverly Place, Suite 115, Cary, NC	

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 review of the Advanced BR2 Bilirubinometer procedures and review of calibration records 6/21/18, the laboratory failed to follow the manufacturer's instructions for calibration of the Advanced BR2 Bilirubinometer. The Advanced BR2 Bilirubinometer Calibration procedure in the manufacturer's instructions state: "Calibration: Use the 20mg/dL Bilirubin Equivalent for calibration. AT A MINIMUM, CALIBRATION SHOULD BE PERFORMED MONTHLY OR MORE OFTEN IF QUALITY CONTROL VALUES ARE OUT OF RANGE. Test the known standard according to the same procedure for testing samples and controls. Adjust the calibration knob to show the mg/dL concentration assigned to the standard (20 mg /dL)." Random review of the 2017 calibrations performed on the Advanced BR2 Bilirubinometer revealed that the laboratory had not performed calibration on the Advanced BR2 Bilirubinometer in August 2017, September 2017, and October 2017.