Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314780	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric & Adolescent Medicine Of East Memphis Pc	1102 Brookfield Road 2nd Fl, Memphis, 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	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 Beckman Coulter AcT Diff complete blood count (CBC) instrument operator's manual, the calibration records for the Beckman Coulter AcT Diff CBC instrument, quality control records, patient data logs and interview with the technical consultant, the laboratory failed to follow manufacturer's instructions for calibration when it did not perform quality control after calibration in 2017 and 2018 with patients reported. 1. Review of the Beckman Coulter AcT Diff operator's manual revealed the following statement under the section for calibration: "Verify calibration by analyzing one replicate for each level of control." 2. Review of the laboratory's calibration records for the Beckman coulter AcT Diff CBC instrument revealed calibration performed on 6.14.17 at 8:52 am and 6.15.18 at 1:00 pm. 3. Review of the laboratory's quality control records for 6.14.17 and 6.15.18 revealed no quality control was performed after instrument calibration. 4. Review of the patient data logs for 6.14.17 and 6.15.18 revealed the following: 8 patients reported on 6.14.17 after calibration was performed without quality control 2 patients reported on 6.15.18 after

	calibration was performed without quality control 5. Interview with the technical consultant on 11.01.18 at 2:00 pm confirmed the laboratory failed to follow manufacturer instructions for calibration when it did not perform quality control after calibration in 2017 and 2018 with 10 patients reported.