Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1007881	08/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ahwfb Pediatrics Kernersville Main Street	861 Old Winston Road, Suite 101, Kernersville, 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 laboratory's policies and procedures, review of the laboratory's 2017, 2018, and 2019 Coulter AcT diff 2 calibration records, review of manufacturer's instructions, and interview with the laboratory director 8/8/19, the laboratory failed to perform calibration at least once every six months and failed to follow manufacturer's instructions for performing calibration. Findings: 1. The laboratory's "Coulter AcT Diff 2 Analyzer" procedure (revised 7/11/19) states "... Calibration is required every 6 months. ..." Review of 2017, 2018, and 2019 Coulter AcT diff 2 calibration records revealed calibration was performed 10/11/17, 10/11/18, and 5/1/19, but not every six months as required. During interview at approximately 11:15 a.m., the laboratory director stated that there was a change in service personnel during the time the calibration was due in April 2018, so the calibration must have been overlooked. 2. The Coulter AcT diff 2 Operator's manual includes instructions for performing calibration using S-CAL calibrator in section 5.6 "AUTO-CALIBRATION" beginning on page 5-10. Instructions include examples of the records that should be maintained for each calibration, and instructions on page 5-18 state to "verify

	calibration" by running controls. Review of the laboratory's 2017, 2018, and 2019 Coulter AcT diff calibration records revealed the records were incomplete: a. The calibration performed 10/11/17 was missing the post-calibration factors. b. The calibration performed 10/11/18 was missing the post-calibration factors and the calibration summary, and quality control material was tested prior to calibration. c. The calibration performed 5/1/19 was missing the calibrator assay sheet, the post-calibration factors, and the calibration summary, and quality control material was tested prior to calibration. During interview at approximately 1:20 p.m., the laboratory director stated that calibration is routinely performed by a service representative. She stated she was unaware some of the records were missing.