Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1026713	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Alex City Internal Medicine	3368 Highway 280 Suite 220, Alexander City, 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
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 a review of the Hematology calibration records, a review of the Beckman Coulter AcT Diff Operator's Manual, Testing Personnel (TP) #1's review of the patient test records, and an interview with TP #1, the laboratory failed to follow the manufacturer's instructions to perform quality controls after the calibrations, and before running patient samples. This was noted on two of five 2018-2020 calibrations reviewed. The findings include: 1. A review of Hematology records revealed the Beckman Coulter AcT Diff was calibrated on 09/04/2019 at 12:09 PM. However, quality control was not performed until 09/05/2019 at 8:23 AM. The instrument was also calibrated on 11/12/2020 at 11:44 PM without quality control being performed until 11/13/2020 at 8:13 AM . 2. A review of the Beckman Coulter AcT Diff Operator's Guide revealed in Chapter 5 Calibration (Page 5-18) "...17 Verify calibration by running 4C Plus cell control. See coulter 4C Plus Cell Control under Heading 2.2, Running Controls for instructions." 3. During an interview on 12/16/2020 at 12:15 PM, Testing Personnel #1 confirmed the above noted findings, stating 6 patient CBC's (Complete Blood Counts) were performed on 09/04/2019 and 8

	patient CBC's performed on 11/12/2020 after the calibrations were run and before the quality controls were performed the following day.