Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0936907	05/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dba Alabama Oncology	833 Princeton Avenue Sw, Pop Iii, Suite 105a, Birmingham, 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 Cell-Dyn Emerald Operator's Manual, and an interview with Testing Personnel #1, the laboratory failed to follow the manufacturer's instructions to perform quality controls after calibration, and before running patient/proficiency testing samples. This was noted on two of nine 2018-2021 calibrations reviewed. The findings include: 1. A review of Hematology records revealed the Cell-Dyn Emerald was calibrated on 07/20/2020 at 12:10 PM. However, quality control was not performed following the calibration and ten patient samples were tested on 07/20/2020 after 12:34 PM. The instrument was also calibrated on 11/23/2020 at 03:20 PM without quality control being performed following the calibration and five proficiency testing samples were tested on 11/23/2020 after 4:00 PM. 2. A review of the Cell-Dyn Emerald Operator's Manual revealed in Section 11 Quality Control (Page 11-3) "...Quality control specimens must be run and results confirmed to be within acceptable limits before reporting patient results. Abbott recommends you, run controls:...After calibration

	(confirmatory step)..." 3. During an interview on 05/04/2021 at 12:15 PM, Testing Personnel #1 confirmed the above findings for 07/20/2020 and 11/23/2020.